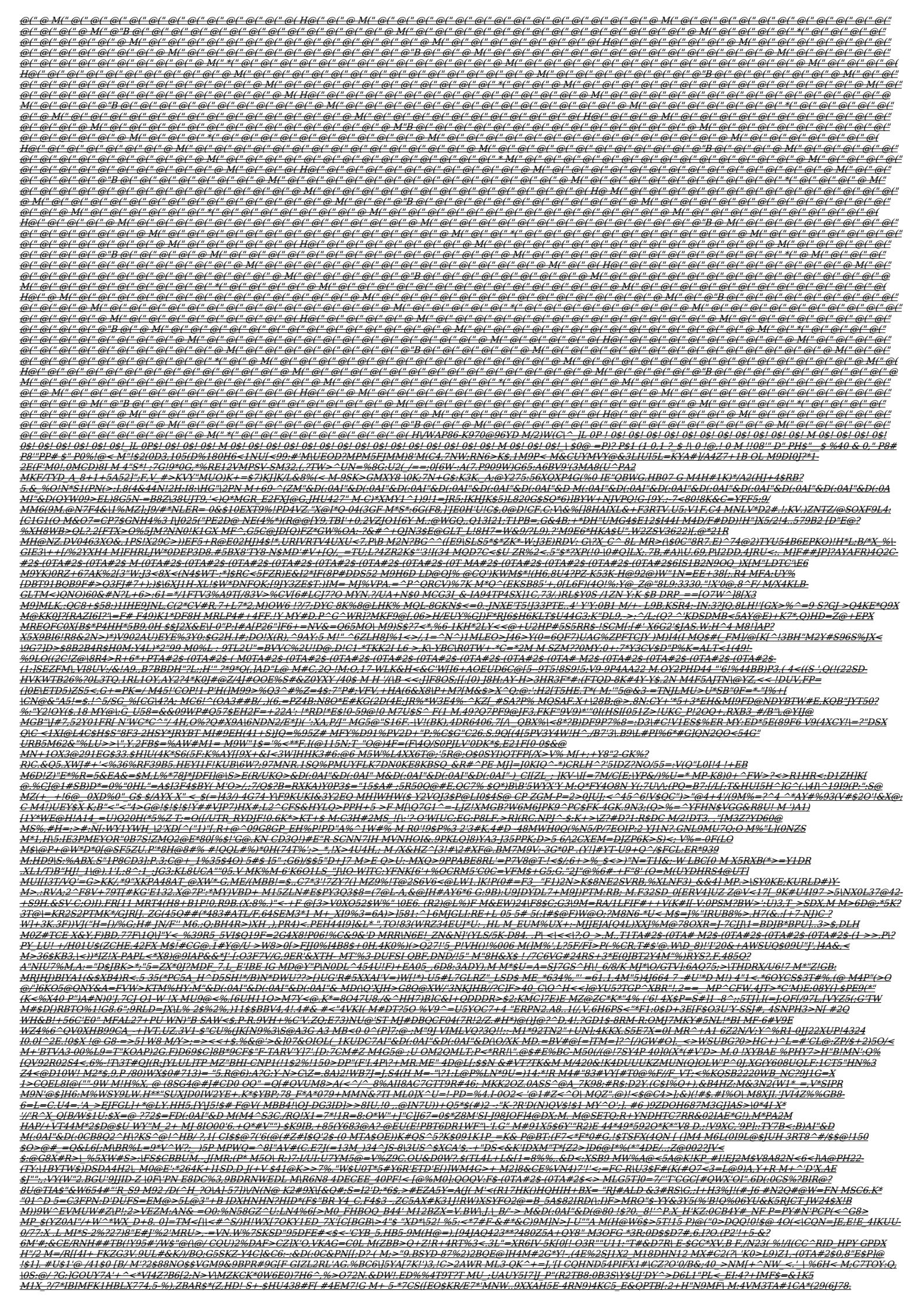

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Â Â UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 Â FORM 10-K Â (Mark One) â˜’ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended October 31, 2024 OR â˜ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO Commission File Number 001-41854 Â enGene Holdings Inc. (Exact name of Registrant as specified in its Charter) Â British Columbia, Canada N/A (State or other jurisdiction ofincorporation or organization) (I.R.S. EmployerIdentification No.) 4868 Rue Levy, Suite 220Saint-Laurent, QC, Canada H4R 2P1(Zip Code) (Address of principal executive offices) Â Registrantâ€™s telephone number, including area code: (514) 332-4888 Â Securities registered pursuant to Section 12(b) of the Act: Title of each class Â TradingSymbol(s) Â Name of each exchange on which registered Common Shares Â ENGN Â The Nasdaq Stock Market LLC Warrants, each exercisable for one Common Share, at an exercise price of $11.50 per share Â ENGNW Â The Nasdaq Stock Market LLC Securities registered pursuant to Section 12(g) of the Act: None Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES â˜ No â˜’ Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes â˜ No â˜’ Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes â˜’ No â˜ Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Â§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes â˜’ No â˜ Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmaller reporting company,â€ and â€œemerging growth companyâ€ in Rule 12b-2 of the Exchange Act. Â Large accelerated filer â˜ Accelerated filer â˜ Non-accelerated filer â˜’ Smaller reporting company â˜’ Â Â Â Â Emerging growth company Â â˜’ Â If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. â˜’ Indicate by check mark whether the registrant has filed a report on and attestation to its managementâ€™s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. â˜ If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. â˜ Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrantâ€™s executive officers during the relevant recovery period pursuant to Â§240.10D-1(b). â˜ Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES â˜ No â˜’ The aggregate market value of the common equity held by non-affiliates of the registrant, based on the closing price of the Common Shares on The Nasdaq Stock Market LLC on April 30, 2024 was $533,605,876. The number of the registrantâ€™s million Common Shares outstanding as of December 16, 2024 was 50,976,676. DOCUMENTS INCORPORATED BY REFERENCEPortions of the definitive proxy statement of enGene Holdings Inc. to be filed for its 2025 annual meeting of shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Auditor Firm Id: 85 Auditor Name: KPMG LLP Auditor Location: Montreal, Canada Â Â Â Â Â Table of Contents Â Page Special Note Regarding Forward Looking Statements 1 Â Â Â PART I Item 1. Business 6 Item 1A. Risk Factors 26 Item 1B. Unresolved Staff Comments 82 Item 2. Properties 82 Item 3. Legal Proceedings 82 Item 4. Mine Safety Disclosures 82 Â PART II Â Item 5. Market for Registrantâ€™s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities 83 Item 6. [Reserved] 84 Item 7. Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations 85 Item 7A. Quantitative and Qualitative Disclosure About Market Risk 102 Item 8. Financial Statements and Supplementary Data 102 Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure 103 Item 9A. Controls and Procedures 103 Item 9B. Other Information 104 Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections 105 Â Â Â PART III Â Â Item 10. Directors, Executive Officers and Corporate Governance 105 Item 11. Executive Compensation 105 Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters 105 Item 13. Certain Relationships and Related Transactions, and Director Independence 105 Item 14. Principal Accountant Fees and Services 105 Â PART IV Â Item 15. Exhibits, Financial Statement Schedules 106 Item 16. Form 10-K Summary 108 Â Â SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS Certain statements in this Annual Report on Form 10-K (the â€œAnnual Reportâ€) may constitute â€œforward-looking statementsâ€ within the meaning of U.S. securities laws and â€œforward-looking informationâ€ within the meaning of Canadian securities laws (collectively, â€œforward-looking statementsâ€). enGeneâ€™s forward-looking statements include, but are not limited to, statements regarding enGeneâ€™s management teamsâ€™ expectations, hopes, beliefs, intentions, goals or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words â€œanticipate,â€ â€œappear,â€ â€œapproximate,â€ â€œbelieve,â€ â€œcontinue,â€ â€œcould,â€ â€œestimate,â€ â€œexpect,â€ â€œforesee,â€ â€œintends,â€ â€œmay,â€ â€œmight,â€ â€œplan,â€ â€œpossible,â€ â€œpotential,â€ â€œpredict,â€ â€œproject,â€ â€œseek,â€ â€œshould,â€ â€œwouldâ€ and similar expressions (or the negative version of such words or expressions) may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this Annual Report may include, for example, statements about: â€¢our financial performance, including financial projections and business metrics and any underlying assumptions thereunder; â€¢our ability to maintain the listing of the Companyâ€™s common shares (â€œCommon Sharesâ€) and warrants to purchase Common Shares (â€œWarrantsâ€) on The Nasdaq Global Market (â€œNasdaqâ€) or another national securities exchange; â€¢our success in recruiting and retaining, or changes required in, officers, key personnel or directors; â€¢our plans and ability to execute product development, manufacturing process development, preclinical and clinical development efforts successfully and on anticipated timelines; â€¢our ability to design, initiate and successfully complete clinical trials and other studies for detalimogene voraplasmid, or detalimogene, formerly referred to as EG-70, and any other product candidates we develop and our plans and expectations regarding our ongoing or planned clinical trials; â€¢the impacts and outcomes of our later-stage and pivotal clinical trials and their influence on obtaining the U.S. Food and Drug Administration (the â€œFDAâ€) or comparable foreign regulatory approval to market detalimogene or any future product candidates; â€¢our plans and ability to seek, obtain and maintain marketing approval from the FDA and other regulatory authorities, including the European Medicines Agency (the â€œEMAâ€), for detalimogene or any other product candidates we develop;

â€¢our plans and ability to commercialize detalimogene or any other product candidates we develop, if approved by applicable regulatory authorities; â€¢the degree of market acceptance of detalimogene or any other product candidates we develop, if approved, and the availability of third-party coverage and reimbursement; â€¢the ability of our external contract manufacturers to support the manufacturing, release testing, stability analysis, clinical labeling and packaging of detalimogene or any other product candidates that we develop; â€¢our future financial performance and the sufficiency of our cash and cash equivalents to fund our operations; â€¢our ability to obtain additional funding on a timely basis; â€¢our ability to effectively manage the transition of executive-level roles to new leaders, and to attract and retain key executives and employees; â€¢the outcome of any known and unknown litigation and regulatory proceedings, including any legal proceedings that may be instituted against us or any of our directors or officers; and â€¢our ability to implement and maintain effective internal controls. All forward-looking statements, including, without limitation, our examination of historical operating trends, are based upon our current expectations and various assumptions. Certain assumptions made in preparing the forward-looking statements include: â€¢we are able to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials and acquire technologies complementary to, or necessary for, detalimogene or any other programs; â€¢we are able to enroll, in a timely manner, a sufficient number of patients in each cohort of the Phase 2 LEGEND trial to assess the efficacy and safety of detalimogene including, the pivotal cohort, the cohort with the BCG-naÃ¯ve patient population, the BCG-exposed patient population and the BCG-unresponsive, papillary-only Ta/T1 disease; â€¢we are able to file our planned Biologics License Application in mid-2026 with the FDA for approval to market detalimogene in the United States as a monotherapy to treat BCG-unresponsive NMIBC with CIS; 1 â€¢detalimogeneâ€™s product profile can be integrated seamlessly into community urology clinics where the vast majority of NMIBC patients are treated; â€¢we are able to retain commercial rights to detalimogene in the United States and commercialize detalimogene independently, while selectively partnering outside of the United States; â€¢we are able to execute the â€œpipeline-in-a-productâ€ development strategy for detalimogene; and â€¢we are able to utilize the DDX gene delivery platform to develop effective, new product candidates for the delivery of genetic medicines to mucosal tissues. You should not place undue reliance on these forward-looking statements which speak only as of the date hereof. The forward-looking statements contained in this Annual Report are based primarily on current expectations and projections about future events and trends that may affect our business, financial condition and operating results. The following uncertainties and factors, among other things (including those described in â€œRisk Factorsâ€ in this Annual Report), could affect future performance and actual results to differ materially and adversely from those expressed in, anticipated or implied by forward-looking statements: â€¢risks applicable to our business, including the heavy dependence on the success of detalimogene and the extensive regulation of all aspects of our business, competition from other existing or newly developed products and treatments; â€¢risks associated with the protection of intellectual property, our ability to raise additional capital to fund our product development activity, and our ability to maintain key relationships and to attract and retain talented personnel; â€¢the possibility that we may be adversely affected by changes in domestic and foreign business, market, financial, political, geopolitical, legal conditions and laws and regulations; â€¢the risk that any regulatory approvals are not obtained, are delayed or are subject to unanticipated conditions that could adversely affect our business; or â€¢other risks and uncertainties set forth in the section entitled â€œRisk Factorsâ€ in this Annual Report. Â In addition, statements that â€œwe believeâ€ and similar statements reflect beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements. Â The forward-looking statements made in this Annual Report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. 2 RISK FACTORS SUMMARY Our business is subject to a number of risks and uncertainties, including those described in Part I, Item 1A. â€œRisk Factorsâ€ in this Annual Report. The principal risks and uncertainties affecting our business includes, among other the following: Risks Related to Our Business â€¢We depend heavily on the success of our lead product candidate, detalimogene voraplasmid, or detalimogene, formerly known as EG-70, which is currently in a clinical trial. Our clinical trial of detalimogene may not be successful. If we are unable to successfully develop, obtain regulatory approval for, and commercialize detalimogene, or experience significant delays in doing so, our business will be materially harmed. â€¢We expect to make significant investments in our continued research and development of detalimogene and other new product candidates, genetic medicines and services we may develop, which, if not successful, would limit our ability to achieve or sustain profitability in the future. â€¢We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the foreseeable future. â€¢The estimates of market sizes and forecasts of market growth for the potential demand of our detalimogene product and any other product candidates we develop are based on a number of assumptions and may prove to be inaccurate. The actual market may be smaller than we believe, which would adversely affect our business and results of operations. â€¢We identified material weaknesses in our internal control over financial reporting and our management has determined that our current internal control over financial reporting is not effective. If we are unable to remedy these material weaknesses, or if we fail to establish and maintain effective internal controls, we may be unable to produce timely and accurate financial statements, and we may continue to determine that our internal control over financial reporting is not effective, which could adversely impact our investorsâ€™ confidence and the price of our Common Shares. â€¢To date, we have not generated any product revenue, have a history of losses and will need to raise additional capital to fund our operations. If we fail to obtain necessary financing, we will not be able to complete the development and commercialization of detalimogene or our other product candidates. â€¢We face significant competition from other entities, including biotechnology and pharmaceutical companies, which may result in our competitors discovering, developing or commercializing products before us or more successfully than we do. Our business and results of operations could be adversely affected if we fail to compete effectively. â€¢We are focusing our research and development efforts on detalimogene, as well as further development of our genetic medicine platform and other product candidates we may develop. As a result, we may forego or delay pursuit of other genetic medicine technologies or other therapeutic product candidates that provide significant advantages over our platform or product candidates, which could materially harm our business and results of operations. â€¢Detalimogene and our genetic medicine platform are based on proven novel technologies, which makes it difficult to predict the time and cost of development and the probability or timing of subsequently obtaining regulatory approval. â€¢Development of new therapeutics involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs, fail to replicate the positive results from our earlier preclinical or clinical studies of our product candidates in later preclinical studies or clinical trials or experience delays in completing or ultimately be unable to complete, the development and commercialization of any product candidates, including but not limited to detalimogene. â€¢Interim top-line and preliminary data from our clinical trials will change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. â€¢If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected. â€¢Although we have conducted the Phase 1 portion of the LEGEND clinical study of detalimogene, we have not as an organization completed later-stage or pivotal clinical trials or submitted a BLA (as defined below), and we may be unable to do so for detalimogene or any future product candidates in a timely manner or at all. â€¢Our use of third parties to manufacture, develop and test our therapeutic product candidates for preclinical studies and clinical trials increases the risk that we will not have sufficient quantities of our product candidates or products, or necessary quantities of such materials on time or at an acceptable cost. â€¢Detalimogene is complex to manufacture, and the manufacturing process for any other product candidates we develop may be similarly complex or more complex, and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of our third-party manufacturers with whom we contract encounter these types of difficulties, our ability to supply detalimogene or any other product candidates we develop for clinical trials or as products 3 for patients, if approved, could be constrained, delayed or stopped, or we may be unable to maintain a commercially viable cost structure. â€¢The market opportunities for detalimogene and any other product candidates we develop may be limited to a small group of patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate. â€¢We depend on our executive team, and if we do not successfully manage the previously announced transitions of our Chief Executive Officer and other executive officers, or if we lose one or more of our executive officers or key employees or are unable to attract and retain highly skilled employees, such events could harm our business. â€¢Our research and development initiatives, manufacturing processes and business depend on our ability to attract and retain highly skilled scientists and other specialized individuals. We may not be able to attract or retain such qualified scientists and other specialized individuals in the future due to the competition for qualified personnel among life science and technology businesses. â€¢Nearly all aspects of our activity and our products and services are subject to extensive regulation by various U.S. federal and state agencies and regulatory bodies in non-U.S. jurisdictions, and compliance with existing or future regulations could result in unanticipated expenses or limit our ability to offer our products and services. Regulatory approval is a lengthy, expensive, and inherently unpredictable process with uncertain outcomes and cost and is subject to the potential for substantial delays. We cannot give any assurance whether or when our product candidates will receive regulatory approval, which is necessary before they can be commercialized. â€¢We cannot predict whether or when we will obtain regulatory approval to commercialize detalimogene or any other product candidate we may develop in the United States or any other jurisdiction and any such approval may be for a narrower indication than we seek. â€¢If we are not able to obtain or if there are delays in obtaining required regulatory approvals for detalimogene or any other product candidates that we may develop, our ability to generate revenue will be adversely affected. Even if we eventually gain approval for detalimogene or any other product candidates, we may be unable to commercialize them. â€¢We may not obtain or maintain regulatory approval of detalimogene or other product candidates we develop in all jurisdictions in which such approval may be required or otherwise desirable or beneficial from a business perspective, and failure to do so may have a material adverse effect on our business and results of operations. â€¢Our contract manufacturers are subject to significant regulation with respect to the manufacturing of our current and future product candidates. The manufacturing facilities on which we rely may not meet or continue to meet regulatory requirements and/or may have limited capacity. â€¢Drug marketing, price controls and reimbursement regulations may materially affect our ability to market and receive coverage for our product candidates, if approved, in the European Union, the United Kingdom, Japan and other non-U.S. jurisdictions. â€¢Global economic uncertainty, changes in geopolitical conditions and weakening product demand caused by political instability, changes in trade agreements and disputes, such as armed conflicts between Russia and Ukraine and in the Middle East, and other macroeconomic factors, could adversely affect our business and results of operations. â€¢If we are unable to obtain and maintain, enforce and defend patent protection for any product candidates we develop or for our novel genetic medicine platform, or if the scope of the patent protection obtained is not sufficiently broad, our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected. 4 Risks Related to our Common Shares and Warrants and to Being a Public Company â€¢Sales of Common Shares, or the perception of such sales, by us or the Selling Holders in the public market or otherwise could cause the market price for our Common Shares to decline and certain Selling Holders still may receive a significant rate of return. â€¢Certain existing securityholders acquired their securities in our Company at prices that may be below the current trading price of such securities, and may experience a positive rate of return based on such current trading price. Future investors in our Company may not experience a similar rate of return. â€¢There is no assurance that Warrants will be and/or remain â€œin the moneyâ€ prior to their expiration or that the holders of Warrants will elect to exercise any or all of their Warrants for cash; the Warrants may expire worthless. â€¢We will continue to incur increased costs as a result of operating as a public company, and the requirements for public companies may strain resources and divert managementâ€™s attention. â€¢We may be unable to satisfy Nasdaqâ€™s continued listing requirements in the future, which could limit investorsâ€™ ability to effect transactions in our securities and subject us to additional trading restrictions. Â 5 PART I Item 1. Business. Background enGene Holdings Inc. (together with its consolidated subsidiaries â€œenGeneâ€ or the â€œCompanyâ€) formed in connection with the Merger Agreement (as defined below), was incorporated as 14963148 Canada Inc. under the federal laws of Canada on April 24, 2023 and changed its name to enGene Holdings Inc. on May 9, 2023. On October 31, 2023, enGene Holdings Inc. continued from being a corporation incorporated under and governed by the Canada Business Corporations Act to a company continued to and governed by the Business Corporations Act (British Columbia). Forbion European Acquisition Corporation (â€œFEACâ€) was a special purpose acquisition company (â€œSPACâ€), incorporated as a Cayman Island exempted company on August 9, 2021 and formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more business or entities. On October 31, 2023 (the â€œClosing Dateâ€), the Company, FEAC, and enGene Inc., consummated the merger (the â€œReverse Recapitalizationâ€ or the â€œBusiness Combinationâ€) pursuant to a business combination agreement, dated as of May 16, 2023 (the â€œMerger Agreementâ€). As a result of the Reverse Recapitalization, the Company became a publicly traded company, and listed its Common Shares and Warrants on the Nasdaq Global Market under the symbols â€œENGNâ€ and â€œENGNW,â€ respectively, commencing trading on November 1, 2023, with Old enGene, a subsidiary of the Company, continuing the existing business operations. Overview We are a clinical-stage biotechnology company focused on developing genetic medicines to improve the lives of patients suffering from bladder cancer. We are developing non-viral genetic medicines based on our novel and proprietary dually derived chitosan, or â€œDDXâ€, gene delivery platform, which allows localized delivery of complex genetic cargos directly to mucosal tissues and other organs. Our lead product candidate, detalimogene voraplasmid, or detalimogene, formerly known as EG-70, is a therapy designed to generate a local immune reaction in proximity to tumors. We believe this enables the immune system to durably clear the tumor and develop memory to resist recurrence. Because this treatment is designed to work by delivering genetic cargo to the broader tumor tissue environment rather than tumor cells specifically, we believe it has the potential to be widely utilized across tumor types. Currently, we are developing detalimogene as a monotherapy to treat non-muscle invasive bladder cancer (â€œNMIBCâ€) with carcinoma in situ (â€œCISâ€) in patients that have been unresponsive to treatment with Bacillus Calmette-GuÃ©rin, or â€œBCG,â€ or what is referred to as â€œBCG-unresponsive NMIBC with CIS.â€ We are also exploring the clinical application of detalimogene to other forms of NMIBC, namely, papillary-only BCG-unresponsive NMIBC (i.e., NMIBC without CIS), as well as BCG-naÃ¯ve NMIBC patients with CIS and BCG-exposed NMIBC patients with CIS (i.e., patients who have been treated with some BCG but who do not qualify as BCG-unresponsive in accordance with FDA and urology practice guidelines). In NMIBC, carcinoma in situ, or CIS, is a flat, high-grade tumor that has a high likelihood of invading the deeper layers of the bladder wall. A â€œhigh-â€ or â€œlow-â€ tumor risk describes the degree to which the tumor pathology appears more likely to grow quickly and invade non-cancerous tissue. NMIBC with CIS is typically initially treated with a solution containing the bacterium BCG that is instilled into the bladder multiple times over the course of several months. Despite this treatment, many of these cancers recur and become unresponsive to additional BCG, allowing the cancer to spread throughout, and deeper into, the bladder often requiring surgical removal of the bladder (this procedure is called a radical cystectomy). We believe patients with BCG-unresponsive NMIBC with CIS are currently underserved with limited FDA-approved treatment options, and that there is a market opportunity for detalimogene as a monotherapy for patients with this condition. While the potential market for detalimogene may not ultimately be limited to these patients, that is our current initial focus in working to bring detalimogene to market. Within the United States, we estimate that there are approximately 83,000 new patients each year diagnosed with bladder cancer, of which up to 80% present with non-muscle invasive disease. Bladder cancer also poses a long-term management burden with an estimated 730,000 people living with disease. See â€œâ€" Lead Product Candidate and Pipeline Development â€" Lead Program: NMIBC Background and Unmet Needâ€ for further information. Our detalimogene program is currently enrolling patients in a combined Phase 1/2 open-label study with a pivotal cohort, referred to as â€œLEGENDâ€ (ClinicalTrials.gov identifier NCT04752722). The Phase 2 portion of LEGEND is enrolling three cohorts: cohort 1 is a pivotal cohort enrolling BCG-unresponsive NMIBC patients with CIS; cohort 2 is enrolling BCG-naÃ¯ve NMIBC patients with CIS (cohort 2a) and BCG-exposed NMIBC patients with CIS (cohort 2b); and cohort 3 is enrolling patients with BCG-unresponsive NMIBC who have papillary disease only (i.e., no CIS). In addition, our preclinical research is focused on expanding the cancer indications that can be treated with detalimogene as well as discovering new opportunities to apply our DDX technology platform to treat other indications with high unmet medical needs. 6 Our Competitive Strengths â€¢Detalimogene Product Candidate Demonstrated Compelling Preliminary Data in Phase 2 of LEGEND â€" We are developing detalimogene, which has received FDA Fast Track designation, as a monotherapy for patients with BCG-unresponsive NMIBC with CIS who we believe are underserved with limited FDA-approved treatment options. The preliminary data collected from all ongoing Phase 2 LEGEND cohorts (data cutoff date of September 13, 2024) demonstrated that detalimogene was generally well-tolerated across all patients dosed, with no patients experiencing a grade 3, 4 or 5 treatment-related adverse event (â€œTRAEâ€) and no drug-related discontinuations. Of the 42 patients in the safety analysis, 20 patients (47.6%) experienced any grade TRAE, 17 patients (40.5%) experienced a Grade 1 TRAE, nine patients experienced a Grade 2 TRAE. The most common TRAEs (â‰¥10%) were dysuria (eight Grade 1; one Grade 2), bladder spasm (four Grade 1; four Grade 2), pollakiuria (five Grade 1; no Grade 2) and fatigue (three Grade 1; two Grade 2). Based on preliminary data corresponding to the September 13, 2024 data cut-off, detalimogene has also demonstrated promising clinical activity in the pivotal Phase 2 portion of the LEGEND study (i.e., cohort 1). More specifically, across 21 patients included in the preliminary data, a 71% complete response rate (CR rate) at any time was observed (15/21), along with a 3-month CR rate of 67% (14/21), a 6-month CR rate of 47%(8/17), and a 6-month Kaplan-Meier CR estimate of 51%. â€¢Product Profile Tailored to the Practical Needs of Clinicians and Patients â€" Genetic medicines and genetic medicine products, such as oncolytic viruses have historically been associated with specific handling or dosing requirements designed for safety reasons to minimize patient, physician, or environmental exposure or risk. These can include use of enhanced personal protective equipment during preparation and administration, required virucidal decontamination of drug product-exposed bodily fluids such as urine after exposure to the genetic medicine product, preparative treatment of tissues with a solvent or wash agent, enhanced refrigeration/cold chain storage requirements, and guidance to avoid close personal contact with the patient during the treatment period. By contrast, we believe detalimogene can be handled in accordance with biosafety level 1 guidelines, should not require the aforementioned precautions in handling or decontamination of fluids or bodily surfaces following dosing when handled in accordance with most institutional or standardized guidelines and has no ultra cold chain on-site storage requirements. We believe these product characteristics, among others, will position detalimogene, if approved, as a preferred choice among both physicians and patients. â€¢â€œPipeline-in-a-Productâ€ Potential â€" Through the combined data generated in the LEGEND study and corresponding preclinical studies, we have demonstrated that detalimogene is able to traverse the mucosal barrier and transfect the underlying epithelial tissues, drive expression of multiple cargos in transfected tissues, and simultaneously activate multiple arms of the immune system. We have further demonstrated in preclinical models the potential for expanding detalimogene to treat multiple additional solid tumors. â€¢Scalable, Proprietary Manufacturing Process â€" We developed the DDX platform in-house, and in addition, have developed manufacturing processes to produce detalimogene that we believe are robust, cost- effective, and scalable. These manufacturing processes, which involve incorporation of plasmid DNA with the DDX carrier at a defined concentration and mixing rate using commercially available equipment, are patent-protected and involve proprietary know-how. We also have a global, royalty-bearing, non-exclusive license to use certain patents and know-how relating to a proprietary plasmid DNA backbone for high-yield production and efficient expression of transgene in target tissues. We believe we have scaled up our manufacturing processes to a level that will be able to meet the needs of commercial launch for detalimogene. We believe our manufacturing process is in accordance with current Good Manufacturing Practice (cGMP) and quality system regulations for drugs and biologics. â€¢Proprietary â€œNext-Generationâ€ DDX Platform â€" We believe our DDX platform has the potential to be the next generation platform that takes genetic medicine beyond rare diseases and into the mainstream of patient care. It has a high degree of payload flexibility, including the ability to conveniently deliver multiple genes (including DNA and RNA) in a single drug product, and has been demonstrated in preclinical animal and in vitro models to effectively induce expression of therapeutic genes in mucosal tissues following delivery to the urinary tract, lung, and gastrointestinal tract, among other organs, all without integration of the genetic cargo into the hostâ€™s genomic DNA. We believe products developed using the DDX platform can overcome many of the significant challenges that have historically faced genetic medicine, including immunogenicity, safety concerns, limited efficacy, high cost of goods, lack of commercially viable manufacturing technology, limited ability to effectively target localize diseases, systemic toxicity, and difficulties with effective administration. â€¢Experienced Management Team â€" Our management team has extensive experience across oncology and multiple other therapeutic areas and modalities and is well-equipped to lead our drug development and commercialization efforts. Our Strategy â€¢Focus on advancing our lead product candidate detalimogene through late-stage clinical development and seek regulatory marketing approval in the United States. We are focused on bringing detalimogene to market as a monotherapy for patients with BCG-unresponsive NMIBC with CIS who we believe are currently underserved by the standard-of-care of radical cystectomy, a major surgery that often results in mortality, a reduced quality of life, and other significant negative outcomes. In response to this urgent unmet need, the FDA has issued guidance for the design of clinical studies for development of novel NMIBC treatments, with a goal of encouraging development of alternative treatments to 7 this drastic surgery. We have followed this guidance and discussed our detalimogene development plan with the FDA, and after these discussions, the FDA cleared us to initiate the Phase 2 portion of the LEGEND clinical trial, including the pivotal portion (Cohort 1). In the pivotal Cohort 1, we are evaluating the safety and efficacy of multiple cycles of detalimogene in patients who have BCG-unresponsive NMIBC with CIS. We currently aim to file a Biologics License Application (â€œBLAâ€) with the FDA in mid-2026 for approval to market detalimogene in the United States as a monotherapy for BCG-unresponsive NMIBC with CIS, and we believe detalimogeneâ€™s product profile will integrate seamlessly into community urology clinics where the vast majority of NMIBC patients are treated. â€¢Build a fully integrated company by independently commercializing approved products in indications and key geographies where we believe we can maximize the value of detalimogene and any other product candidates we develop. We currently own all development and commercialization rights for our detalimogene. To bolster our potential return on investment, we currently plan to retain commercial rights to detalimogene in the United States and commercialize detalimogene independently, while selectively partnering outside of the United States, with the goal of leveraging a potential partnerâ€™s regional expertise and existing sales force to the extent appropriate. â€¢Explore additional clinical applications of detalimogene voraplasmid within high risk NMIBC. Given the persistent high unmet need in high-risk NMIBC outside of the BCG-unresponsive population with CIS, we are enrolling additional cohorts of patients in the Phase 2 LEGEND trial to assess detalimogene in other indications such as BCG-NaÃ¯ve NMIBC with CIS, BCG-exposed with CIS, and BCG-unresponsive, papillary-only disease. â€¢We believe we can potentially develop detalimogene as a treatment for other forms and stages of bladder cancer, including applications within NMIBC and beyond. For example, we have shown in a murine preclinical orthotopic model of locally advanced bladder cancer that i) administration of detalimogene drives profound and durable anti-tumor immunity, and ii) cured mice exhibit resistance to subsequent local or distal re-challenge with bladder tumor cells due to detalimogeneâ€™s potentiation of a T-cell mediated response within the adaptive immune system. These preclinical observations support detalimogeneâ€™s immunostimulatory mechanism of action and speaks to its potential in more aggressive or advanced diseases where the bladder remains intact, such as locally advanced or metastatic bladder cancer. We further believe that to the extent detalimogene proves to be both safe and effective in more aggressive, high-risk NMIBC populations, it also will have the potential for use in earlier stage low- and intermediate-risk NMIBC populations. â€¢Apply our proprietary DDX platform to other mucosal tissues. We believe that our clinical data to date demonstrate the value and the breadth of our DDX platform in delivering genetic medicines to mucosal tissues, especially when combined with our preclinical proof-of-concept studies. We believe this could allow us to use our DDX platform to develop safe and effective new agents beyond detalimogene, thereby unlocking better outcomes for historically difficult-to-treat conditions. Our belief is driven by our DDX platformâ€™s numerous advantages and points of differentiation relative to other approaches to genetic medicine, which we believe will enable us to apply such medicines beyond their traditional tissues of application such as the liver, muscle, and central nervous system. Importantly, we have also developed a streamlined, end-to-end cGMP manufacturing process that we believe can support commercial launch of detalimogene and can be readily applied to new drug products. Lead Product Candidate and Pipeline Development Our lead product candidate is detalimogene voraplasmid, which we are developing as a monotherapy for the treatment of NMIBC via the LEGEND study, a multi-cohort Phase 2 open-label study comprised of single-arm cohorts (ClinicalTrials.gov identifier NCT04752722). Cohort 1 of LEGEND, which is enrolling BCG-unresponsive NMIBC patients with CIS, is pivotal, and we plan to incorporate the data from this study in a BLA that we plan to submit following the conclusion of the Phase 2 portion of the Cohort 1. In addition to this pivotal cohort, LEGEND is also enrolling two additional cohorts and three patient groups: cohort 2a is enrolling BCG-naÃ¯ve NMIBC patients with CIS; cohort 2b is enrolling BCG-exposed NMIBC patients with CIS; and cohort 3 is enrolling patients with BCG-unresponsive NMIBC who have papillary disease only (i.e., no CIS). 8 The following chart shows the current status of our product development: Â Detalimogene voraplasmid Mechanism of action Our detalimogene drug product candidate comprises lyophilized nanoparticles, which in turn comprise DNA nanoplasmid encapsulated by a non-viral, DDX polymer-based delivery vehicle. The DDX delivery vehicle, a unique technology proprietary to enGene, consists of a highly derivatized chitosan backbone and includes reversible PEGylation (where PEG stands for polyethylene glycol) to facilitate diffusion through the non-cellular, GAG (glycosaminoglycan) layer in the bladder. The detalimogene drug substance plasmid DNA encodes three distinct genes: a single-chain interleukin-12 protein (IL-12) and two non-protein coding RNA products, eRNA11a and VA1, which collectively stimulate the retinoic acid-inducible gene I (RIG-I) pathway. Together, this combination of RIG-I activation and IL-12 secretion serves to activate both innate and adaptive immunity, creating a pro-inflammatory, tumor-killing environment: Â Â Mechanistically, detalimogeneâ€™s dual RIG-I agonists work by initiating a signaling cascade that results in the production of Type I interferons (IFN) and proinflammatory cytokines upon recognizing certain double stranded RNA molecules typically associated with cellular pathogens. This in turn stimulates a potent inflammatory response that results in direct tumor cell killing, cytokine-mediated activation of innate immune cells, and the recruitment and cross-priming of T cells. Detalimogeneâ€™s third genetic cargo, IL-12, is an immunomodulatory cytokine that signals primarily through the IL-12 receptor complex, which is expressed on natural killer (NK), NK-T, and activated effector CD4+ and CD8+ T cells. For these cells, receptor engagement of IL-12 enhances cytotoxicity, e.g., by driving T cell proliferation, polarization to a type 1 helper (Th1) phenotype, and interferon-gamma (IFNg) production. In summary, the activation of RIG-I is intended to induce an innate immune response that will trigger T cell recruitment and cross-presentation of tumor antigens to T cells through induction of mediators such as C-X-C motif chemokine ligand 10 (CXCL10) and Type I IFNs, respectively. The 9 expression of the IL-12 protein is intended to synergistically augment the anti-tumor activity of indwelling effector T cells. Together, RIG-I agonism and IL-12 receptor stimulation function in a two-step mechanism to recruit and activate immune cells to the tumor microenvironment (â€œTMEâ€). Importantly, detalimogene does not need to transfect tumor cells specifically to drive the above effects and can exert its anti-tumor effect by transfecting healthy epithelial cells within the tumor or bladder microenvironment. Importantly, we believe restricting expression of IL-12 to the bladder and tumor microenvironment yields meaningful safety advances. This is important as historically, clinical trials using systemic administration of IL-12 to treat various solid malignancies have resulted in severe dose-limiting toxicities, resulting in a marginal therapeutic window. We believe the clinical data observed to date demonstrate that coupling the potent stimulation of the innate immune system by RIG-I agonism to stimulation of the adaptive immune response by IL-12 provides robust and persistent anti-tumor activity. Lead Program: NMIBC Background and Unmet Need Disease Background Bladder cancer represents a serious, life-threatening condition. Based on data reported through 2020, bladder cancer is expected to result in an estimated 2.7% of all cancer deaths in 2023 while comprising an estimated 4.2% of all new cancer cases according to the National Institute of Health. Overall, according to the American Cancer Society and the National Institute of Health, the chance men will develop this cancer during their life is about 1 in 28; and for women, the chance is about 1 in 91. Fortunately, due to early warning signals such as hematuria (the presence of blood in the urine), many instances of bladder cancer are diagnosed while still localized to the bladder urothelium. These tumors, referred to as non-muscle invasive bladder cancer (NMIBC), represent approximately 80% of newly diagnosed bladder tumors. Unmet Medical Need When diagnosed at the non-muscle invasive stage, the goal of treatment is to prevent further tissue invasion (e.g., into the muscle layers of the bladder or beyond), thereby potentially reducing the intensity of needed treatment regimens (e.g., allowing local/intravesical treatment versus systemic/intravenous treatment) and forestalling surgical bladder removal, if indicated. Since the 1970s, the primary therapy for high-risk NMIBC has been intravesical BCG therapy and/or transurethral resection of bladder tumor surgery (TURBT), despite the adverse effects of both treatment approaches. Due to the increased use of BCG in the high-risk, CIS-containing setting and loss of several manufacturers of BCG, supply constraints have resulted in a shortage of the BCG for commercial use. To manage the limited supply available in the United States, as of February 2019, the American Urological Association and their collaborative physician groups have introduced rationing guidelines that limit use of BCG to high-risk NMIBC patients only. This situation is projected to continue late into the current decade and has brought urgency to the unmet medical need for effective intravesical treatments for patients with high grade NMIBC, according to the American Urological Association. We estimate that there are approximately 83,000 new patients each year diagnosed with bladder cancer in the United States, of which up to 80% are initially diagnosed with NMIBC. Within this group, we estimate approximately 30% present with high-risk NMIBC (where risk level describes the risk of disease progression to muscle invasion), 35% present with intermediate-risk disease, and 35% present with low-risk disease. NMIBC lesions are further characterized as CIS, Ta, and T1 based on their physical attributes. Ta and T1 lesions are papillary urothelial carcinomas which have not yet penetrated the muscle wall of the bladder. These tumor types are not mutually exclusive within the bladder; at any given time, an NMIBC patient can have papillary lesions only, CIS and papillary lesions, or CIS lesions only. In general, while most NMIBC patients respond favorably to treatment (e.g., transurethral resection of bladder tumor surgery (TURBT) and/or treatment with BCG), we estimate that as many as 60% will experience a recurrence within one year, depending on the patient and tumor characteristics. For patients with BCG-unresponsive NMIBC, standard therapy has been radical cystectomy or treatment with systemic therapy, both of which have been associated with significant toxicities and complications, including a lower quality of life, and increased treatment-related morbidity and mortality. No salvage medical or intravesical treatments have been shown to have durable efficacy in BCG-unresponsive NMIBC patients and therefore, there is an unmet medical need for novel non-systemic therapies to treat these patients. This recurrent population represents a population of patients with a need to keep their cancer from becoming invasive while being able to preserve their bladders. Importantly, we believe that the frequency of newly incident high-risk NMIBC per year does not fully capture the number of patients living with this disease. This is because there are multiple channels through which a patient previously diagnosed with low- or intermediate-risk NMIBC may, through the course of their treatment and disease evolution, ultimately present with high-risk disease. For example, a patient whose tumor was initially diagnosed and treated as low- or intermediate-risk NMIBC may recur as high-risk NMIBC. Similarly, a patient treated for BCG-unresponsive high-risk NMIBC with CIS may recur a second time with another high-risk NMIBC lesion and be eligible for another round of treatment. Thus, we believe that the real-world high-risk NMIBC burden is best understood as a combination of both incident and prevalent disease. Unfortunately, for individuals with BCG-unresponsive NMIBC with CIS, which represents the focus of LEGENDâ€™s pivotal cohort, FDA-approved non-surgical treatment options remain limited. Study Design LEGEND is a Phase 1/2, open-label, multicenter, safety and dose-finding study conducted in the United States that is currently enrolling a pivotal Phase 2 study cohort in adult patients with NMIBC with CIS who have failed BCG therapy and who are recommended for radical cystectomy. The study consists of two phases, beginning with a now-completed Dose-Escalation Phase (Phase 1). The key 10 objective for the Phase 1 portion of the study was evaluation of safety and tolerability and selection of a dose for the Phase 2 portion and it was not designed to evaluate efficacy in a statistically meaningful way. While not statistically powered for efficacy, an evaluation of efficacy was a secondary objective, with a Phase 2 study to be conducted at the recommended dose. Eligible BCG-unresponsive NMIBC patients with CIS were enrolled in Phase 1 and patients with these criteria are being enrolled in cohort 1 of Phase 2, which has already begun. In addition to the pivotal cohort 1, the Phase 2 portion of LEGEND is enrolling two additional cohorts: cohort 2 is enrolling patients with BCG-naÃ¯ve NMIBC patients with CIS (cohort 2a) and BCG-exposed NMIBC patients with CIS (cohort 2b); and cohort 3 is enrolling patients with BCG-unresponsive NMIBC who have papillary disease only (i.e., no CIS). Phase 1 The Phase 1 portion of the study was an open-label, multi-dose study designed to evaluate the safety of detalimogene high-risk BCG-unresponsive NMIBC patients with CIS, with or without co-occurring papillary disease to help determine an appropriate dose for the Phase 2 portion of LEGEND. This study enrolled a total of 24 patients across multiple dose groups. Phase 1 Study Design All patients in Phase 1 received at least one cycle of treatment with detalimogene. A cycle is 12 weeks or approximately three months in duration, which corresponds to exploratory efficacy endpoint of the Phase 1 study (see below). Those patients who have complete response (CR) or stable disease (SD) at the end of the first three-month treatment cycle may (in association and consultation with their physician) optionally elect to continue receiving treatment for up to a total of four cycles, provided they do not have progressive disease (PD) on evaluation for response at the end of each cycle. Patients who complete cycle 1 and the additional 3 cycles without PD are followed until PD or for approximately 2 years following their End-of-Treatment Visit, whichever occurs first. In general, we use the terminology â€œ3-month,â€ â€œ6-month,â€ â€œ9-month,â€ and â€œ12-monthâ€ timepoint to refer to 12-week, 24-week, 36-week, and 48-week timepoints, respectively. We use these terms interchangeably. Phase 1 Study Endpoints The primary endpoint of the Phase 1 study was safety (i.e., characterizing the nature, incidence, relatedness and severity of all observed adverse events (â€œAEsâ€) and severe adverse events (â€œSAEsâ€)), with complete response at 3 months and pharmacodynamics of biomarkers assessed as exploratory endpoints. Phase 1 Results: Safety Twenty-four patients received at least one dose of detalimogene in the Phase 1 study, with the total number of treatment-related adverse events (TRAEs) and most commonly reported TRAEs across all 24 patients defined in the table below. The majority (75%) of TRAEs experienced by patients were Grade 1 or 2 and largely consistent with the same events seen with instrumentation, catheterization, and instillation of any intravesical agent. One Grade 3 TRAE was observed in Phase 1. However, on review, it was observed that the patient had a history of renal failure and recurrent obstructive uropathy prior to treatment that was present at screening, and the enrollment criteria for LEGEND were subsequently modified to exclude patients with similar medical history. There was no association between the severity or incidence of AEs and the dose level. In addition, TRAEs were not more frequent or severe in later cycles of dosing. The following table summarizes the Phase 1 safety results. Â Phase 1 Results: Efficacy Efficacy at 3 months was assessed by the standard three criteria evaluation used for NMIBC, namely urinary cytology, cystoscopic appearance (i.e., an inspection with a cystoscopeâ€"a thin tube with video camera that is inserted into the bladder), and biopsy results of suspicious areas. Biopsies in the former area of CIS were required even if the appearance was normal. In Phase 1, patients without progressive disease were allowed to electively continue study drug after the 3-month visit. In total, 22 patients were dosed with the study drug and evaluable for efficacy at the 3-month visit. One patient included in evaluations for safety evaluation was excluded from efficacy. 11 Overall, across all doses, 16 of 22 patients dosed with detalimogene achieved a CR rate at any time of 73%. At the 3-month timepoint, this CR rate was 68% (15 of 22), with 82% (18 of 22) of patients continuing to receive additional doses of the study drug beyond 3 months. The 6-month CR rate across all doses was 45% (10 of 22). Within the dose selected for the pivotal portion of the study, the CR rates at 3 and 6 months were 70% and 60%, respectively, with 90% of patients continuing on the study drug beyond 3 months. Phase 2 Study The Phase 2 portion of the study is open-label and is comprised of three independent single arm cohorts of patients. Cohort 1, the pivotal cohort, is enrolling high-risk BCG-unresponsive NMIBC patients with CIS, with or without co-occurring papillary disease. Cohort 2 is enrolling high-risk, BCG-naÃ¯ve NMIBC patients with CIS (cohort 2a) or high-risk BCG-exposed NMIBC patients with CIS (cohort 2b). Cohort 3 includes high-risk BCG-unresponsive papillary only NMIBC patients. Although the treatment is the same for each cohort, an independent set of analysis will occur for each cohort. In Phase 2, cycles are 12 weeks in duration and dosing will occur at weeks 1, 2, 5 and 6 of each 12-week cycle. Patients will be administered 800Âµg/ml intravesically at each dosing. On September 26, 2024, we announced important amendments to the LEGEND Phase 2 protocol that, when fully implemented, will modify how patients are evaluated and treated at key points in their therapy. The amended LEGEND protocol stipulates that, at the end of the first 12-week cycle, patients will be evaluated as follows: (i) patients with no evidence of high-risk tumor will be classified as being in complete response (CR), will remain on-study, and enter the next 12-week course of therapy; (ii) patients with CIS or high-risk Ta disease or a combination thereof will be classified as not in complete response (non-CR), will remain on-study (to allow their tumors additional time to respond to detalimogeneâ€™s immunostimulatory mechanism of action), and will enter the next 12-week course of therapy; and (iii) patients with high-risk T1 (which has a higher risk of progression than CIS or high-risk Ta) or more advanced disease will be classified as non-CR and will not be eligible to continue on-study (and, if appropriate, will be advised to consider radical cystectomy so as to reduce the risk of further disease progression). For all subsequent evaluation cycles beyond week 12 (e.g., weeks 24, 36, 48, and beyond), the presence of any high-risk tumor in the bladder will render a patient ineligible to continue on-study. More specifically, (i) patients with no evidence of high-risk tumor will be classified as CR, remain on-study, and enter the next 12-week course of therapy, whereas (ii) patients with biopsy-confirmed evidence of CIS, high-risk Ta, or high-risk T1 disease or greater will be classified as non-CR and will discontinue the study. Patients who have continued CR at week 48 will enter a maintenance treatment for up to four 12-week cycles through week 96. Maintenance treatment will consist of 2 instillations per 12-week cycle, administered at week 1 and at week 2. Patients with CR at the end of the 8 cycles (week 96) can choose to continue in maintenance treatment for up to 4 more cycles (through week 144) or enter a follow-up period for quarterly visits (every 12 weeks) through week 144 or until non-response. Percentage of patients with CR at 48 weeks, based on cystoscopic appearance, urine cytology, and appropriate biopsies will be the co-primary endpoint together with the nature, incidence, relatedness, and severity of treatment emergent adverse events. Secondary endpoints will include progression free survival, CR rates at 12, 24, 36, and 96 weeks, as well as CR rate by 24 weeks, and the duration of response of the responding patients. On September 26, 2024, we shared preliminary data from the first 21 patients who had reached their 12-week evaluation in the ongoing pivotal cohort of the LEGEND study, including 17 patients who were also assessed at six months. The CR rate at any time was 71%, the CR rate at three months was 67% and the CR rate at six months was 47%. The data cutoff date was September 13, 2024. 12 The overall tolerability profile associated with detalimogene was favorable, and there have been no drug-related discontinuations in the study. Of the 42 patients assessed for safety, inclusive of all Phase 2 cohorts, 20 patients (48%) experienced at least one treatment-related adverse event (TRAE), which were mainly Grade 1/2 in severity. The most common TRAEs (10%) were dysuria, bladder spasm, pollakiuria and fatigue. There were no Grade 4 or Grade 5 TRAEs reported. Â Detalimogene voraplasmid: Design and Mechanism of Action Detalimogene contains a non-integrative plasmid DNA (pDNA) packaged in our proprietary DDX delivery platform that is further combined with the excipient polyethylene glycol-b-poly-L-glutamic acid (PEG-b-PLE), a di-block co-polymer. Â 13 The pDNA component of detalimogene encodes the two linked subunits (p40 and p35) of the human (h) IL-12 cytokine. Also encoded within the same plasmid are two RNA products (adenoviral VA RNA1 (VA1) and eRNA11a; annotated together as eRNA41H) that coordinate to activate RIG-I. The dsRNA directly induces the intracellular protein RIG-I, while VA1 is an inhibitor of adenosine deaminase acting on RNA (ADAR), an RNA editing enzyme, and the double-stranded RNA-dependent protein kinase (PKR), a protein translation inhibitor. Together, VA1 and eRNA11a synergistically boost RIG-I activity. Analysis of intravesical mEG-70 treatment in an orthotopic bladder cancer model To evaluate the therapeutic benefit of detalimogene voraplasmid preclinically, an orthotopic model of murine bladder cancer was established by implanting syngeneic MB49 urothelial carcinoma cells that stably express luciferase (MB49luc) into murine bladders. Baseline tumor burden was confirmed by bioluminescence using in vivo imaging before two weekly IVI of mEG-70, a murine-reactive surrogate for detalimogene voraplasmid, with the study design captured in the top panel of the figure below. mEG-70 mediated a dose-dependent reduction of pre-existing tumor burden as evidenced by diminished bioluminescent signal on Day 29 of the study. Note in the figure below, the right panel displays individual animals, with the color scale indicating the intensity of the tumor signal, from blue (lowest) to red (highest), and areas without color indicating a lack of tumor. The graph on the left displays the geometric mean across all animals, Â± 95% confidence interval. Â We further examined the durability of the anti-tumor response by monitoring long-term survival until all mice succumbed to bladder cancer or were deemed cured, which was defined as no evidence of bioluminescent signal with no clinical signs of bladder cancer, including palpable bladder mass and hematuria. Over 90% of mice treated with mEG-70 had durable anti-tumor responses as demonstrated by long-term disease-free survival with no disease relapse during the 100-day monitoring period. In contrast, about 90% of sham-treated animals had succumbed to disease during the same period. We believe these data demonstrate the rapid, robust, and durable anti-tumor effects of mEG-70 in the orthotopic model of bladder cancer. Long-term effects, immunological memory, and systemic immunity mediated by mEG-70 We believe that the long-term survival benefit and lack of relapse in mEG-70-treated animals suggested that immunological memory may have been established. To further explore this, we examined protective immunity against tumor re-challenge, wherein mEG-70-treated mice with complete disease regression and no relapse (â€˜mEG-70-curedâ€™) were re-challenged orthotopically with MB49luc cells to assess protection from recurring disease. All mEG-70-cured mice were resistant to tumor recurrence, as shown by negative bioluminescence signal up to 3 weeks after re-challenge. In contrast, indicative of tumor burden, all age-matched naÃ¯ve controls had positive bioluminescence signal following cell implantation (figure below; bottom panel displays luminescence from each individual animal reflecting tumor burden from luciferase expression with the color scale indicating the intensity of the tumor signal, from blue 14 (lowest) to red (highest), and areas without color indicating a lack of tumor; top panel reflects geometric means Â± 95% confidence interval). Â As shown in the figure below, to determine if local treatment to the bladder results in systemic anti-tumor immunity, mice cured of orthotopic bladder cancer by mEG-70 were challenged with MB49luc cells subcutaneously on the flank and tumor growth was monitored. Although age-matched naÃ¯ve controls showed rapid tumor growth, all mEG-70-cured mice remained tumor free up to 50 days post-rechallenge. To investigate whether the abscopal anti-tumor immunity was specific to MB49luc cells, a separate cohort of mice was re-challenged with antigenically distinct melanoma tumor cells (B16-F10). Although mEG-70-cured mice were resistant to re-challenge with MB49luc cells, the B16-F10 tumors grew on the mouse flank, suggesting that long-term anti-tumor effect is antigen-driven and specific to the primary tumor. Â Other Bladder Cancer Indications Our preclinical data package utilizes the MB49 cancer cell line, which, when instilled into the bladder of a mouse, can generate tumors reflective of muscle invasive bladder cancer. We believe that the preclinical data we have gathered using this murine model system, especially the data suggesting mEG-70 drives a potent immune memory effect that renders the host resistant to tumor re-challenge, could potentially support the use of detalimogene in other forms of bladder cancer, such as muscle invasive disease, as well as other forms of NMIBC such as intermediate-risk disease. Commercialization Strategy In accordance with our clinical development plan, we are planning to file a BLA for detalimogene for the treatment of NMIBC patients who are BCG-unresponsive with CIS in 2026 based on the expected Phase 2 results from the pivotal cohort of the LEGEND study, if the results are positive. If the FDA grants us marketing approval for detalimogene in the United States, we currently plan to commercialize detalimogene in the United States ourselves. Our current plan is to establish a U.S.-focused sales and marketing organization to coordinate with high-prescribing community urology centers in the United States. As part of our commercialization strategy, our plan is to also establish a specialty urologic medical science liaison team to support scientific exchange with and education 15 of physicians and scientists about detalimogene. To proactively support these efforts, we will seek to continue expanding our relationships with key opinion leaders as well as our trial investigators while expanding physician and patient education about the potential benefits of detalimogene versus alternative therapies. We have not yet determined our commercialization strategy outside of the United States. The additional cohorts in Phase 2 of the LEGEND study, in which we propose to treat BCG-naÃ¯ve, BCG-exposed, and papillary-only NMIBC patients, provide further opportunity to demonstrate the potential use of detalimogene in clinical settings with unmet need that have also been affected by critical drug shortages; these cohorts thus represent another important component of our commercialization plan. To the extent that detalimogene shows promise in these patient populations, we will share the results of the study with key opinion leaders and urology community leaders, with the aim of building credibility and support for our therapy and increasing interest in its use among urologists and healthcare providers in FDA-approved indications. We believe the urology community will benefit from detalimogeneâ€™s relative ease of use and handling, among other benefits. If supported by the data, we may choose to pursue further trials to support labeling, some of which may be pivotal. Manufacture and Supply Detalimogene voraplasmid is a nanoparticle suspension containing the plasmid deoxyribonucleic acid (pDNA) drug substance encapsulated in a proprietary polymer, DDX, and further combined with a custom-manufactured methoxy-poly(ethylene glycol)-block-poly(L-glutamic acid) diblock co-polymer (abbreviated as PEG-b-PLE). DDX and PEG-b-PLE are novel excipients. The drug product is formulated as an aqueous nanoparticle dispersion, filter sterilized, lyophilized to a dry powder, and stored at -20Â°C. We do not currently own or operate any manufacturing facilities for the clinical or commercial production of drug product. We have leveraged our internal expertise and know-how to develop and scale up the manufacturing processes for our proprietary DDX and drug product before transferring them to qualified external contract manufacturers or CMOs. Additionally, we are conducting studies to understand and establish controls for all critical process parameters and critical quality attributes for our drug product. The PEG-b-PLE excipient and pDNA drug substance are custom manufactured and purchased from qualified cGMP manufacturers located in the European Union. All critical excipients, drug substance and drug product are currently manufactured at cGMP-compliant CMOs at a scale that we believe can meet our needs for a commercial launch of detalimogene for the BCG-unresponsive NIMBC indication in the United States following FDA approval. We believe that our manufacturing processes are robust, cost-effective and scalable. These manufacturing processes are patent-protected and involve significant proprietary know-how. We also have a global, royalty-bearing, non-exclusive license to use certain patents and know-how relating to a proprietary plasmid DNA backbone for high-yield production and efficient expression of transgene in target tissues. Our manufacturing process is in accordance with current Good Manufacturing Practice (cGMP) and quality system regulations for drugs and biologics. We currently rely on our commercial relationships with independent CMOs to supply our clinical trials. We have performed detailed quality audits in the past and will continue to conduct periodic quality audits of their facilities per existing quality agreements. We believe that our suppliers will be capable of providing sufficient quantities of each component to meet our clinical trial supply needs, as well as our commercial launch within the United States if and when approved by the FDA. We have supply agreements in place with multiple CMOs to support manufacturing, release testing, stability analysis, clinical labeling and packaging of detalimogene for the Phase 2 portion of the LEGEND study. We plan to enter into long term commercial supply agreements with selected qualified CMOs to supply detalimogene in the event that we are granted marketing approval in the United States. Other CMOs may be used in the future for commercial manufacturing. Intellectual Property Our commercial success depends in part on our ability to protect, obtain, enforce and maintain exclusivity around our gene delivery technology and product candidates through intellectual property protection, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others and to prevent others from infringing, misappropriating or otherwise violating our proprietary rights. We strive to protect, maintain, enforce and enhance the proprietary technology, inventions and improvements that are commercially material to our business, including by seeking, maintaining and defending our patent rights. We have and are expecting to maintain granted patents, and we continue to file and prosecute patent applications directed to our modified oligomeric chitosan-based nanoparticle gene delivery technology independently or in combination with therapeutic genes in an effort to establish intellectual property positions relating to new compositions of matter and novel treatments of various indications. We also rely, in part, on trade secrets and know-how to maintain exclusivity to our technology. We strive to protect our proprietary information that is not covered by registered intellectual property instruments by entering into confidentiality and invention assignment agreements with employees, collaborators and consultants. While protecting trade secrets and know-how presents challenges due to, for 16 example, movement of personnel and the natural evolution of the knowledge in the field of our technology over time, we strive to actively manage exchanges of information with third parties to minimize the risks of dissemination. Patent Portfolio Our patent portfolio includes composition of matter, method of treatment and manufacturing process protection for our lead product candidate detalimogene. We have taken a multi-tiered approach to our patent strategy, and in doing so we have captured a series of sequential technical developments leading to and incorporated within detalimogene. â€¢First, as of October 31, 2024, we own two patent families comprising seven granted U.S. patents, two pending U.S. non-provisional applications, and 85 corresponding granted foreign patents and pending foreign patent applications in jurisdictions including Australia, Brazil, Canada, China, Eurasian Patent Organization, the European Patent Office, Austria, Belgium, Switzerland, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hong Kong, Hungary, Ireland, Italy, Luxembourg, Latvia, Macedonia, Netherlands, Norway, Poland, Portugal, Sweden, Slovenia, Slovakia, Turkey, Israel, India, Japan, Philippines, Republic of Korea, Mexico, New Zealand, Singapore and South Africa with claims directed to the dual-derivatization scheme that constitutes the core of our DDX-based gene delivery platform, including granted and pending composition of matter claims relating to the nature of the hydrophilic polyol used in the dual derivatization scheme, as well as methods of use and treatment. The U.S. and foreign patents directed to this subject matter will expire between 2033 and 2034, absent any applicable patent term extension or patent term adjustment. â€¢Second, as of October 31, 2024, we own one patent family comprising one U.S. non-provisional application and 15 corresponding granted foreign patents and pending foreign patent applications pending in jurisdictions including Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Philippines, Singapore and South Africa with claims directed to the non-covalent, reversible coating of our nanoparticle technology for enhanced delivery, which we have recently developed and incorporated into detalimogene, which enhances transfection and gene expression. The pending claims include compositions of matter and methods of use, and the patents issuing from this patent family, if any, will expire in 2040, absent any applicable patent term extension or patent term adjustment. â€¢Third, as of October 31, 2024, we own one patent family comprising one U.S. non-provisional application and 15 corresponding foreign patent applications pending in jurisdictions including Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Philippines, Singapore and South Africa with claims directed to the unique combination of immunological cargos, IL-12 and RIG-1 agonists, that are delivered in detalimogene, including composition of matter claims relating to alternatives to our RIG-I agonists, as well as methods of using same in the treatment of mucosal cancers. The patents issuing from this patent family, if any, will also expire in 2040, absent any applicable patent term extension or patent term adjustment. â€¢Fourth, as of October 31, 2024, we own one patent family comprising one granted U.S. patent, one pending U.S. non-provisional application, and six corresponding granted foreign patents and pending foreign patent applications in jurisdictions including Australia, Canada, China, the European Patent Office, Israel and Japan with claims directed to the use of our chitosan-based nanoparticle gene delivery technology in the treatment of various inflammatory gut disorders. The patents issuing from this patent family will expire in 2037, absent any applicable patent term extension or patent term adjustment. In this patent family, U.S. Patent No. 11,603,398 received a patent term adjustment of 154 days thereby extending the expiry date to at least April 12, 2038. â€¢Fifth, as of October 31, 2024, we own one patent family comprising one U.S. non-provisional application and four corresponding foreign patent applications pending in jurisdictions including Australia, Canada, the European Patent Office and Hong Kong with claims directed to the use of our chitosan-based nanoparticle gene delivery technology in the treatment of various lung disorders. The patents issuing from this patent family, if any, will expire in 2041, absent any applicable patent term extension or patent term adjustment. â€¢Sixth, as of October 31, 2024, we own one patent family comprising one U.S. non-provisional application and 15 corresponding foreign patent applications pending in jurisdictions including Australia, Brazil, Canada, China, the European Patent Office, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Philippines, Singapore and South Africa with claims directed to the use of detalimogene in the treatment of various metastatic cancers, based on data obtained in one of the cancer models. The patents issuing from this patent family, if any, will expire in 2042, absent any applicable patent term extension or patent term adjustment. â€¢Seventh, as of October 31, 2024, we own one patent family comprising two granted U.S. patents and corresponding granted foreign patents in jurisdictions including Australia, the European Patent Office, Belgium, Switzerland, Germany, France, United Kingdom, Ireland, Liechtenstein, Netherlands, Hong Kong, and New Zealand with claims directed to the use of low molecular weight chitosan in oral gene delivery, including composition of matter and method of use claims. The US and foreign patents directed to this subject matter will generally expire in 2027, absent any applicable patent term extension or patent term adjustment. In this patent family, U.S. Patent No. 8,846,102 received a patent term adjustment of 1737 days thereby extending the expiry date to at least December 31, 2031, and U.S. Patent No. 9,404,088 received a patent term adjustment of 736 days thereby extending the expiry date to at least April 4, 2029. 17 â€¢Eighth, as of October 31, 2024, we own one patent family comprising three granted U.S. patents and 28 corresponding granted foreign patents in jurisdictions including Australia, Canada, China, the European Patent Office, Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, United Kingdom, Ireland, Iceland, Italy, Netherlands, Norway, Poland, Portugal, Sweden, Slovenia, Hong Kong, Israel, Japan, Republic of Korea, Mexico, India and Singapore with claims directed to certain methods of manufacturing our nanoparticles, including composition of matter, methods of making, and product-by-process claims. The US and foreign patents directed to this subject matter will expire in 2028, absent any applicable patent term extension or patent term adjustment. In this patent family, U.S. Patent No. 8,722,646 received a patent term adjustment of 327 days thereby extending the expiry date to at least August 19, 2029. â€¢Finally, we have one pending PCT application directed to the optimized clinical treatment protocol for detalimogene in the treatment of bladder cancer, based on the LEGEND study (NCT04752722). The patents issuing from this patent family, if any, will expire in 2044, absent any applicable patent term extension or patent term adjustment. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing of the first non-provisional patent application to which priority is claimed. In the United States, patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years beyond the expiration of the patent under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension involves a complex calculation based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. There is no guarantee that the applicable authorities will agree with our assessment of whether any extensions should be granted, and if granted, the length of these extensions. Our general filing strategy regarding registrable intellectual property is to seek patent protection in major markets. For example, our core DDX-based gene delivery technology is protected by issued patents in the United States, Europe (with country coverage within Europe), Japan, China, Hong Kong, India, Eurasia, South Korea, Canada, Australia, New Zealand, Brazil, Mexico and several other jurisdictions. Our filing strategy typically involves the filing of an international PCT patent application followed by national filings in specific countries. The selection of countries is made on a case-by-case basis. Our patent portfolio currently comprises nine patent families, which include approximately 133 issued patents and 49 pending patent applications, including 12 issued U.S. patents, four issued European patents (with country coverage within Europe), six non-provisional pending U.S. applications, five European pending applications and one pending PCT application. enGene exclusively owns all nine patent families in its patent portfolio. The patent positions of companies like us are generally uncertain and involve complex legal, scientific, and factual questions. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents or will be commercially useful in protecting our commercial products and methods of using and manufacturing the same. We also cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold or control may be challenged, circumvented or invalidated by third parties. In addition, our agreements and security measures protecting our trade secrets and know-how may be breached, and we may not have adequate remedies for any such breach. Further, our trade secrets may otherwise become known or independently discovered by competitors. See â€œRisk Factorsâ€”Risks Related to Our Intellectual Propertyâ€ for important information about risk related to our intellectual property. Strategic License Agreement On April 10, 2020, we entered into a non-exclusive license agreement (the â€œLicense Agreementâ€) with Nature Technology Corporation (â€œNTCâ€) pursuant to which NTC granted enGene a worldwide non-exclusive, royalty-bearing and sublicensable license to certain patents and know-how relating to the NanoplasmidTM vector backbone that is used in detalimogene voraplasmid to research, develop, make, use, import, sell and offer to sell, any gene and cell therapy products incorporating the NanoplasmidTM vector backbone (excluding any such products in the field of dermatology). The licensed intellectual property includes 10 patent families (inclusive of 18 all related divisional, continuation, continuation-in part, substitutes, counterparts and/or any foreign equivalents filed in any country within such family) and certain know-how. NTC is solely responsible for the preparation, filing, prosecution, cost and maintenance of all patent applications and patents included in the licensed intellectual property. Unless terminated earlier, the License Agreement will continue until no valid claim of any licensed patent exists in any country. NTC may terminate the License Agreement if we fail to make any payments within a specified period after receiving written notice of such failure. Either party may terminate the License Agreement in the event either party commits a material breach and fails to cure such breach within a certain period. We can terminate the License Agreement for convenience with prior notice to NTC. Under the License Agreement, we are obligated to make annual payments of $50 thousand until the first sale of a product for which a royalty is due and make a payment to NTC of $50 thousand upon assigning the License Agreement to a third-party. We are also required to make a one-time payment of $50 thousand for the first dose of a product covered by a valid claim of a licensed patent (a â€œMilestone Productâ€) in the first patient in a Phase 1 clinical trial or, if there is no Phase 1 clinical trial, in a Phase 2 clinical trial, as well as a one-time payment of $450 thousand upon regulatory approval of a Milestone Product by the FDA. The first milestone related to the first dose of a Milestone Product was achieved during the year ended October 31, 2021. The second milestone, regulatory approval of a Milestone Product, has not been achieved as of the year ended October 31, 2024. We are also required to pay NTC a royalty percentage in the low single digits of the aggregate net product sales in a calendar year by us, our affiliates or sublicensees on a product-by-product and country-by-country basis, as long as the composition or use of the applicable product is covered by a valid claim in the country where the net sales occurred. Royalty obligations under the License Agreement will continue until the expiration of the last valid claim of a licensed patent covering such licensed product in such country. In the event that we or any of our affiliates or sublicensees manufacture any GMP lot of a licensed product, then we or any such affiliate or sublicensee will be obligated to pay NTC an amount per manufactured gram of GMP (or its equivalent) lot of product, which varies based on the volume manufactured. Such manufacturing payment will expire on a product-by-product basis upon receipt of regulatory approval to market a product in any country in the licensed territory. Under the License Agreement, enGene is permitted to sublicense our rights to third parties and we are not required to share any of the license revenue with NTC. NTC was acquired by Aldevron, LLC in January 2022. The terms of the existing License Agreement described above remained the same. Competition The biotechnology and pharmaceutical industries are characterized by rapid innovation of new technologies, fierce competition, and strong defense of intellectual property. While we believe that detalimogene and our knowledge, experience and scientific resources provide us with competitive advantages, we may face competition from pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among other things. Many of our competitors, either independently or with strategic partners, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval for treatments and achieving widespread market acceptance. Merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be substantially limited if our competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or less expensive than products we may develop. In geographic locations that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of the entry of our products. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of other drugs. The key competitive factors affecting the success of any products we may develop are likely to be their efficacy, safety, convenience, price and availability of reimbursement. There are four FDA-approved products for the treatment of high risk NMIBC patients that are unresponsive to BCG, and multiple companies have drugs in clinical development for such treatment. While many of these products represent a different modality and may not be either intravesical or monotherapy, they may nonetheless compete with us for patient recruitment in clinical trials as well as for commercial sales. Furthermore, to the extent Merck & Co. (â€œMerckâ€) or another manufacturer increases the supply of BCG, there may be less demand for alternative treatments such as detalimogene in BCG-naÃ¯ve or BCG-exposed patients. In addition, there are numerous companies that have commercialized or are developing treatments for NMIBC, including Aura Biosciences, Inc., AstraZeneca, Bristol Meyers Squibb, CG Oncology Inc., Hoffman-La Roche AG (Roche), ImmunityBio Inc., Johnson & Johnson Inc., Merck, Protara Therapeutics, Inc., Pfizer, Inc., and UroGen Pharma, Inc. Competing products include, among other things, the following FDA-approved products: 19 â€¢AdstiladrinÂ® (nadofaragene firadenovec), a non-replicating adenoviral vector-based genetic medicine that is manufactured and marketed by Ferring Pharmaceuticals A/S. â€¢KeytrudaÂ® (pembrolizumab), a Merck product, for the treatment of patients with high-risk BCG-unresponsive NMIBC with CIS with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy. â€¢VALSTARÂ® (valrubicin), marketed by Endo Pharmaceuticals, an anthracycline topoisomerase inhibitor for intravesical treatment of BCG-refractory CIS of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality. â€¢AnktivaÂ® (nogapendekin alfa inbakicept-pmln), marketed by ImmunityBio, an engineered IL-15 superagonist protein complex that is approved for use in patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors, when administered in combination with BCG. See â€œRisk Factors â€” Risks Related to Our Business â€” We face significant competition from other biotechnology and pharmaceutical companies, which may result in our competitors discovering, developing or commercializing products before us or more successfully than we do. Our business and results of operations could be adversely affected if we fail to compete effectivelyâ€ for important information about risks respecting competition. Regulatory Matters The development, production, testing, distribution, and marketing of biologics like the ones we are developing are subject to strict regulations by various U.S. federal, state, and local agencies in addition to foreign regulatory authorities. These regulations cover a wide range of aspects, including research, safety, efficacy, labeling, packaging, storage, distribution, and advertising, as well as post-approval monitoring and reporting. Our Company, as well as our vendors, partners, contract research organizations (CROs), and manufacturers, will need to comply with these regulations. To gain approval for our product candidate, we need to comply with the regulatory requirements of various governing agencies, including those related to preclinical and clinical trials, manufacturing, and commercialization. This process requires a significant investment of time and financial resources. In the United States, our focus market, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and other federal, state, and local regulations also apply. Our lead product candidate, detalimogene, is not yet approved for marketing in the United States. See â€œRisk Factors â€” Regulatory Risksâ€ for important information about risks respecting regulatory matters. To obtain approval for our product candidates for therapeutic use in the United States, we must follow a series of steps regulated by the FDA. This includes conducting preclinical studies in compliance with regulations, meetings with the FDA, submitting an investigational new drug application, or â€œIND,â€ to the FDA, obtaining institutional review board, or â€œIRB,â€ or ethics committee approval at each clinical trial site, conducting clinical trials in compliance with Good Clinical Practice (â€œGCPâ€) requirements, preparing and submitting a BLA accompanied by fees, undergoing FDA pre-approval inspections of manufacturing facilities, and having potential FDA audits of the clinical trial sites. Finally, the FDA will review and approve the BLA and provide any recommendations before the biologic drug can be sold commercially in the United States. Preclinical and clinical testing of biological drug products In order to test a drug or biologic in humans, it must first undergo extensive preclinical testing, which includes laboratory evaluations and animal studies to determine safety and efficacy. These studies must comply with federal and state regulations, including Good Laboratory Practices (â€œGLPâ€) requirements for safety and toxicology studies. The results of these studies, as well as manufacturing and analytical data, must be submitted to the FDA as part of an IND. The IND is a request for authorization to administer the product to humans and must be approved before clinical trials can begin. The IND submission focuses on the protocol for the initial clinical study and includes results of animal and in vitro studies, as well as any available human data to support the use of the investigational product. The IND becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the study, in which case a clinical hold is imposed until the concerns are resolved. During the clinical stage of development, the product candidate is administered to patients or healthy volunteers under the supervision of qualified investigators in accordance with GCP requirements. Each clinical trial must be reviewed and approved by an IRB to ensure that the risks to individuals participating in the clinical trial are minimized and reasonable in relation to the anticipated benefits. The FDA, IRB, or sponsor may suspend or discontinue a clinical trial at any time on various grounds. Some studies also include oversight by a data safety monitoring board. Clinical trials must be reported to public registries within specific timeframes. While international clinical trials can be conducted under an IND, the FDA does not require that all foreign clinical trials be conducted under United States INDs. The FDA will accept a well-designed and conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection if necessary. Clinical trials that are carried out to determine the efficacy of a drug for the purpose of obtaining marketing approval through a BLA are typically carried out in three phases that can occur simultaneously, in combination, or staggered. 20 Phase 1: Phase 1 of clinical trials involves administering the investigational product to healthy human volunteers or patients with the target disease or condition for the first time. The primary objective of these studies is to evaluate the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, identify any side effects associated with increasing doses, and potentially gather preliminary evidence of effectiveness. Phase 2: Phase 2 clinical trials usually involve giving the investigational product to a small group of patients with a particular disease or condition to assess its effectiveness, determine the best dosage and dosing schedule, and detect any potential risks or side effects. To gather data before conducting more extensive and costly Phase 3 trials, several Phase 2 studies may be conducted. Phase 3: Phase 3 trials usually involve testing the investigational product in a larger group of patients to confirm its efficacy and safety. The trials are conducted at multiple locations and aim to establish the overall risk-benefit profile of the product. Typically, the FDA requires two well-controlled Phase 3 clinical trials to approve a BLA. After marketing approval, Phase 4 clinical trials, also known as post-approval trials, may be conducted to gain more experience with the product in its intended use and to gather additional safety data. The FDA may require these trials as a condition of approval. The results of clinical trials and safety reports for serious adverse events must be submitted to the FDA annually and within 15 days of the sponsorâ€™s determination. Fatal or life-threatening adverse reactions must be reported within seven days. Along with clinical trials, companies must complete additional animal studies, develop information about the productâ€™s biological characteristics, and establish a commercial manufacturing process that adheres to cGMP requirements. The manufacturing process must consistently produce quality batches of the product, and appropriate packaging and storage conditions must be identified through stability studies. Expanded Access Expanded access, also known as â€œcompassionate use,â€ refers to the use of investigational products outside of their intended clinical development to treat patients suffering from serious or life-threatening diseases or conditions when no satisfactory alternative treatment options are available. FDA regulations permit access to investigational products through an IND by the treating physician or the company for treatment purposes, including individual patients, intermediate-size patient populations, and larger populations for use under a treatment protocol or treatment IND application. It is important to note that companies are not obligated to provide expanded access to their investigational products. BLA Submission and marketing authorization by the FDA We plan to apply for either data exclusivity or market exclusivity for our product candidates. If the necessary clinical testing is completed successfully, we will submit the results of preclinical studies and clinical trials, as well as detailed information on the productâ€™s manufacturing, labeling, and other aspects, to the FDA in the form of a BLA. This application seeks approval to market a new biologic for one or more specific indications. The BLA must contain all relevant data from both positive and negative studies. The BLA should incorporate all important information accessible from relevant preclinical and clinical examinations, including negative or questionable outcomes as well as certain discoveries, along with itemized data connecting with the itemâ€™s science, assembling, controls, and proposed naming, in addition to other things. Information might come from organization supported clinical preliminaries planned to test the wellbeing and viability of an itemâ€™s utilization or from various elective sources, including review started by examiners. The data submitted must be of sufficient quality and quantity to satisfy the FDA regarding the investigational productâ€™s safety, purity, and potency in order to support marketing approval. A BLA must be approved by the FDA before a biologic can be sold in the United States. A BLA or supplement to a BLA must also include data to assess the biological product candidateâ€™s safety and effectiveness for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, as required by the Pediatric Research Equity Act, or PREA. An initial Pediatric Study Plan (PSP) must be submitted within sixty days of an end-of-Phase 2 meeting or as agreed upon between the sponsor and FDA by a sponsor planning to submit a marketing application for a biological product that includes a new clinically active component, new indication, new dosage form, new dosing regimen, or new route of administration. PREA does not apply to any biological product for an indication for which an orphan designation has been granted, unless otherwise required by regulation. In some cases, the FDA may also request additional information before deciding whether or not to accept the BLA for filing. Within 60 days of receiving a BLA, the FDA must decide whether or not to accept it for filing. This decision may include refusing to file. The FDA begins a comprehensive substantive review of the BLA as soon as the submission is accepted for filing. A BLA is reviewed by the FDA to see, among other things, if the product is safe, pure, and effective, and if the facility where it is manufactured, processed, packaged, or stored satisfies standards designed to guarantee the productâ€™s continued safety, quality, and purity. Under the objectives and policies consented to by the FDA under the Prescription Drug Users Fee Act, or PDUFA, once a BLA has been submitted, the FDAâ€™s goal for novel biological products generally is to review the application within ten months after it accepts the application for filing, or, if the application is granted priority review, six months after the FDA accepts the application for filing. The FDA does not always meet its PDUFA goal dates, and the review process may be extended. For example, the review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional data, analysis or information that the FDA deems a major amendment. 21 Further, under PDUFA, as changed, each BLA should be joined by a client charge, and the patron of an endorsed BLA is likewise dependent upon a yearly program expense. FDA changes the PDUFA client expenses on a yearly premise. In some cases, fees may be reduced or waived. For example, a small business may not have to pay the application fee for the first time. In addition, unless the product also includes a non-orphan indication, there are no user fees associated with BLAs for products designated as orphan drugs. See â€œOrphan drug designation and exclusivityâ€ below. The FDA might allude an application for a biologic to a warning board of trustees. A panel of independent experts, such as clinicians and other scientific experts, is known as an advisory committee. It reviews, evaluates, and offers a recommendation, such as whether the biologic is sufficiently safe and effective in a particular indication for a particular population and under what conditions. While an advisory committeeâ€™s recommendations do not bind the FDA, they are carefully taken into consideration when deciding whether or not to grant marketing approval. The FDA will typically conduct an inspection of the facility or facilities where the product is manufactured prior to approving a BLA. The FDA will not approve an application unless it finds that the manufacturing facilities and processes are adequate to guarantee consistent product production in accordance with the required specifications. Furthermore, prior to approving a BLA, the FDA might investigate at least one clinical preliminary destination to guarantee consistence with GCP and different necessities and the uprightness of the clinical information submitted to the FDA. The FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to be submitted as a condition for approving a BLA to ensure that the productâ€™s benefits outweigh its risks. The REMS may include medication guides, communication plans, assessment plans, or other risk-minimization tools. Once the BLA and all related information, including advisory committee recommendations and inspection reports, have been evaluated, the FDA may issue an approval letter or a Complete Response Letter. A Complete Response Letter indicates that the application is not ready for approval and lists all deficiencies found in the BLA. The FDA may recommend actions the applicant can take to improve the BLAâ€™s chances of approval. Even with additional information, the FDA may still reject the application. If the FDA approves a product, it may impose restrictions, require additional studies, or limit approved indications for use. The FDA can also impose distribution and use restrictions or other risk management mechanisms under a REMS, which may affect the productâ€™s market and profitability. Post-marketing studies or surveillance programs may result in the FDA limiting or preventing further marketing of the product. Changes to the approved product may also require further testing and FDA review and approval. Expedited drug development and review programs at the FDA The FDA has programs to speed up the development and review of new drugs and biologics for serious or life-threatening diseases. These programs include Fast Track designation, Breakthrough Therapy designation, priority review, and Accelerated Approval. A biologic can get Fast Track designation if it is meant to treat a serious or life-threatening disease and has the potential to address unmet medical needs for that disease. This applies to the product and the specific indication for which it is being studied. Fast Track designation allows sponsors to interact more with the FDA during preclinical and clinical development. There is also potential for rolling review, where the FDA can review parts of the BLA on a rolling basis if the sponsor provides a schedule, the FDA accepts the schedule, and the sponsor pays required fees when submitting the first section of the BLA. Our lead product candidate, detalimogene, has been granted Fast Track designation by the FDA. There can be no assurance that detalimogeneâ€™s Fast Track designation will lead to a faster development, regulatory review or approval process or increase the likelihood that detalimogene will receive marketing approval. Breakthrough Therapy designation is given to drugs that demonstrate a substantial improvement over existing therapies on clinically significant endpoints, and this designation provides intensive guidance for an efficient development program. Products with Fast Track or Breakthrough Therapy designation may also be eligible for priority review and Accelerated Approval. Priority review is given to drugs that provide significant improvement in safety or effectiveness for serious or life-threatening diseases or conditions. Accelerated Approval is given when a drug has an effect on a surrogate or early clinical endpoint that is likely to predict clinical benefit. Sponsors must agree to conduct additional post-approval studies to verify clinical benefit, and the FDA may withdraw approval if those studies fail. While these programs may expedite the development or review process, they do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval. 22 Post-Approval Requirements The FDA heavily regulates drugs and biologics that are manufactured or distributed with their approval. This includes requirements related to recordkeeping, reporting, and product distribution. Companies must comply with promotion and advertising restrictions and are prohibited from marketing or promoting products for unapproved, off-label uses. Failure to comply with these requirements can result in penalties and liability under the False Claims Act (the â€œFCAâ€). Post-approval requirements may include post-market testing and surveillance to assess the productâ€™s safety and effectiveness. Manufacturers and their subcontractors must register with the FDA and undergo periodic inspections for compliance. Changes to the manufacturing process may require FDA approval. Failure to comply can result in legal or regulatory action, and the FDA can withdraw approval if regulatory standards are not maintained. Revisions to approved labeling and other restrictions may also be imposed. In addition, post approval, a pediatric study is typically required unless a waiver is granted. In the case of detalimogene, due to the rare incidence of bladder cancer in children, we may request a waiver of this requirement. The consequences of failing to comply with FDA regulations include various restrictions such as limitations on marketing or manufacturing, product recalls, safety alerts, and mandated modifications of promotional materials and labeling. Companies may also face fines, warning letters, untitled letters, or holds on clinical trials and refusal of FDA approvals. The FDA can also take more serious actions such as product seizure or detention, injunctions, or civil or criminal penalties. In addition, companies may face consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs. Orphan drug designation and exclusivity The Orphan Drug Act allows the FDA to give orphan drug designation (â€œODDâ€) to drugs or biologics meant to treat rare diseases or conditions, which are defined as having a patient population of fewer than 200,000 individuals in the United States or a patient population greater than 200,000 individuals in the United States when it is not reasonable to expect that the cost of developing and making the drug available in the United States will be recovered from sales in the United States. To receive ODD, it must be requested before submitting a BLA, and the identity of the therapeutic agent and its potential orphan use are publicly disclosed after ODD is granted. If a product receives ODD and later becomes the first FDA-approved drug for a particular clinically active component for the disease it was designated for, it is entitled to orphan drug exclusivity, meaning the FDA cannot approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years from the approval of the BLA, except under specific circumstances. These circumstances include showing clinical superiority to the product with orphan drug exclusivity or if the holder of the exclusivity cannot assure the availability of sufficient quantities of the drug for patients. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. ODD also offers benefits like tax credits for certain research and a waiver of the BLA application user fee. However, a product with ODD may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received ODD. Moreover, the exclusive marketing rights in the United States may be lost if the FDA later finds that the request for designation was materially defective or if the manufacturer canâ€™t assure sufficient quantities of the product for patients with the rare disease or condition. Biosimilars and Exclusivity The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the â€œACAâ€), signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act (â€œBPCIAâ€), which simplified approval process for biological products that are similar to an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining how to review and approve biosimilars. Biosimilarity requires that the biological product and the reference product be the same in terms of safety, purity, and potency. This can be proven through analytical studies, animal studies, and clinical studies. Interchangeability requires that a product be biosimilar to the reference product and that the biologic, and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy. An application for a biosimilar product cannot be submitted to the FDA until four years after the reference product was licensed by the FDA. Also, the approval of a biosimilar product cannot be made effective until 12 years after the reference product was licensed. During this period, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product that shows the safety, purity, and potency of its product. The BPCIA also created exclusivity periods for biosimilars approved as interchangeable products. It is not yet clear if products deemed â€œinterchangeableâ€ by the FDA will be readily substituted by pharmacies, which are governed by state pharmacy law. In the United States, a biological product may receive additional market exclusivity for six months if the manufacturer voluntarily completes a pediatric study in accordance with an FDA-issued â€œWritten Request.â€ The BPCIA, which created an abbreviated approval pathway for biosimilar products, is complex and continues to be interpreted and implemented by the FDA. Recently, government 23 proposals have sought to decrease the 12-year reference product exclusivity period. Some aspects of the BPCIA, which could affect its exclusivity provisions, have been the subject of litigation. Therefore, the impact, implementation, and regulatory interpretation of the BPCIA remain uncertain. Regulation of combination drug products in the US Combination products are those that are made up of different components, such as biological and device components, that are typically regulated by different FDA centers. According to FDA regulations, a combination product can be a single entity made up of two or more regulated components that are combined in some way, two or more separate products packaged together, or a product that requires the use of an approved drug, device or biological product to achieve the intended effect. The FDA assigns a lead center for review of combination products based on the productâ€™s primary mode of action. The Office of Combination Products has been established to address issues related to combination products and provide guidance and regulations for their regulation. Combination products with a biologic primary mode of action are generally reviewed through the biologic approval process, with input from the device center to ensure the device component meets safety and performance requirements. Combination products are subject to current Good Manufacturing Practice (cGMP) regulations for drugs, biologics, and devices, including quality system regulations for medical devices. Our manufacturing process is cGMP compliant. Other regulatory considerations for drug products After a product candidate has been approved or commercialized, its manufacturing, sales, promotion, and other related activities are subject to regulation by various regulatory bodies in the United States. In addition to the FDA, these regulatory authorities may include the Centers for Medicare & Medicaid Services (the â€œCMSâ€), other divisions of the Department of Health and Human Services (the â€œHHSâ€), the Drug Enforcement Administration (the â€œDEAâ€), the Consumer Product Safety Commission, the Federal Trade Commission (the â€œFTCâ€), the Occupational Safety & Health Administration, the Environmental Protection Agency, as well as state and local governments and agencies. Drug coverage and reimbursement In the United States and many other countries, patients rely on third-party payors to cover part or all of the costs of their treatment. Having sufficient coverage and reimbursement from government healthcare programs and private insurers is critical for the success of new products. The availability of coverage and reimbursement will impact our ability to commercialize our product candidates, and the amount of reimbursement provided may not be enough for us to make a profit. Government authorities and third-party payors determine which medications they will pay for and at what level. New products may not be covered or may have limited coverage, and the reimbursement level may be lower than necessary to cover our costs. The COVID-19 pandemic has also caused uncertainty regarding insurance coverage, as many people have lost their employer-based coverage. The factors that payors consider when determining reimbursement include whether the product is covered by the plan, safe, effective, medically necessary, appropriate for the patient, and cost-effective. Discounts and rebates required by government programs and private payors may reduce the net price for drugs, and there is increasing pressure on drug companies to offer predetermined discounts. We cannot be certain that reimbursement will be available for our products or what the reimbursement level will be, and we may be subject to penalties if we do not report pricing metrics accurately and in a timely manner. We also cannot be certain that if we obtain reimbursement arrangements with payors that such arrangements will not be subject to recoupment actions or overpayment challenges, which can be time consuming and expensive to resolve. Health care laws and regulations in the United States Pharmaceutical companies must comply with various healthcare regulations enforced by the federal government and state and foreign authorities where they do business. These regulations limit financial arrangements and relationships involving the research, sale, marketing, and distribution of products authorized for sale. The laws include the federal Anti-Kickback Statute (â€œAKSâ€), which prohibits offering or receiving remuneration for referrals or purchases that may be paid under federal and state healthcare programs. The FCA and Civil Monetary Penalties Law prohibit submitting false claims for payment to the government. The federal Health Insurance Portability and Accountability Act of 1996 imposes liability for executing schemes to defraud healthcare benefit programs or falsifying information related to healthcare delivery and payment. The â€œSunshine Actâ€ requires manufacturers of reimbursable drugs, devices, biologics, and medical supplies to report physician payments and other transfers of value. The Health Insurance Portability and Accountability Act (â€œHIPAAâ€) imposes privacy and security obligations on certain healthcare providers, health plans, and healthcare clearinghouses. Similar state laws may apply to sales and marketing arrangements involving healthcare items or services reimbursed by non-governmental third-party payors, reporting requirements related to financial arrangements with clinicians, and state privacy and security laws governing health information can be different from HIPAA. Noncompliance with these laws can lead to significant penalties, including administrative, civil, and criminal penalties, damages, fines, disgorgement, restructuring of operations, oversight and reporting obligations, and exclusion from participation in federal and state healthcare programs. 24 Healthcare legislative development Healthcare payors, whether they are government or private entities, are using more sophisticated methods to control costs, but these methods are not always suitable for new technologies like genetic medicine and treatments for rare diseases. Legislative and regulatory changes to the healthcare system in the United States and many other countries could affect our ability to sell our products profitably. The ACA, which became law in 2010, introduced a range of changes, including subjecting biologic products to competition from lower-cost biosimilars, increasing minimum Medicaid rebates, and imposing new annual fees and taxes on certain branded prescription drugs. The ACA has faced legal and political challenges, and the Biden administration has initiated a special enrollment period and ordered reviews of policies and rules that limit access to healthcare. Other healthcare reform measures may also impact our business. Since the ACA was enacted, other legislative changes have been proposed and adopted in the United States, including spending reductions under the Budget Control Act of 2011 and the Right to Try Act, which provides a federal framework for certain patients to access investigational new drug products. There has also been growing interest in specialty drug pricing practices and efforts to control pharmaceutical and biological product pricing at the federal and state levels, including transparency measures and importation from other countries. Facilities Our corporate headquarters are located in Montreal, Canada, where we lease and occupy approximately 10,620 sq. feet of laboratory and office space at 4868 Rue Levy, Montreal, QC H4R 2P1. We also maintain office space in the United States at 200 5th Street Waltham, Massachusetts 02451. We believe that our current facilities are sufficient for our current needs. To meet the future needs of our business, we may lease additional or alternate space. We believe that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations. Employees As of October 31, 2024, we had 57 employees, including 56 full-time employees, 26 of whom were primarily engaged in research and development activities. Of these employees, 21 are based in Canada and 36 in the United States. None of our employees are represented by a labor organization or are party to a collective bargaining arrangement. We consider our relationship with our employees to be excellent. Legal Proceedings From time to time, we may be involved in legal proceedings that arise in the regular course of our business. Our management believes that we are not currently involved in any legal proceedings that are likely to have a significant negative effect on our business. However, legal proceedings can negatively affect our business, financial condition, results of operations, and future prospects, regardless of the outcome, due to costs associated with defense and/or settlement, as well as the diversion of management attention and resources, among other factors. 25 Item 1A. Risk Factors. Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under â€œSpecial Note Regarding Forward-Looking Statements,â€ you should carefully consider the specific risks set forth herein. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described in this Annual Report or our other filings with the U.S. Securities and Exchange Commission (the â€œSECâ€) are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business. Risks Related to Our Business We depend heavily on the success of our lead product candidate, detalimogene voraplasmid, or detalimogene, formerly known as EG-70, which is currently in a clinical trial. Our clinical trial of detalimogene may not be successful. If we are unable to successfully develop, obtain regulatory approval for, and commercialize detalimogene, or experience significant delays in doing so, our business will be materially harmed. We currently only have one product candidate, detalimogene, in clinical development. We invested and continue to invest a significant portion of our efforts and financial resources in the research and development of detalimogene. Our ability to generate revenues from the sale of drugs that treat bladder cancer and other diseases in humans, which may not occur for several years, if ever, will depend heavily on the successful clinical development, regulatory approval for, and eventual commercialization of detalimogene. This may make an investment in our Company riskier than similar companies that have multiple product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate. The success of detalimogene will depend on several factors, including: â€¢successful initiation and enrollment of clinical trials and completion of clinical trials with favorable results; â€¢acceptance of regulatory submissions by the FDA or comparable foreign regulatory authorities for the conduct of clinical trials of detalimogene and of our proposed designs of planned clinical trials of detalimogene, including protocol amendments or other changes we may make to ongoing clinical trials; â€¢the frequency and severity of adverse events observed in clinical trials and preclinical studies; â€¢maintaining and establishing relationships with CROs and clinical sites for the clinical development of detalimogene, and the ability of such CROs and clinical sites to comply with clinical trial protocols, GCPs and other applicable requirements; â€¢demonstrating the safety, purity and potency (or efficacy) of detalimogene to the satisfaction of applicable regulatory authorities, including by establishing a safety database of a size satisfactory to regulatory authorities; â€¢receipt and maintenance of regulatory approvals from applicable regulatory authorities, including approvals of BLAs from the FDA; â€¢maintaining relationships with our third-party CMOs and the CMOs' ability to comply with cGMPs as well as entering into agreements with our third-party CMOs for, or establishing our own, commercial manufacturing capabilities at a cost and scale sufficient to support commercialization; â€¢establishing sales, marketing and distribution capabilities and launching commercial sales of detalimogene, if and when approved by the FDA, whether alone or in collaboration with others; â€¢obtaining, maintaining, protecting and enforcing patent and any potential trade secret protection or regulatory exclusivity for detalimogene; â€¢maintaining an acceptable safety profile of detalimogene following regulatory approval, if any; â€¢maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell detalimogene; and â€¢acceptance and coverage of our products, if approved, by patients, the medical community and federal healthcare programs and other third-party payors. If we are unable to develop, obtain regulatory approval for, or if approved, successfully manufacture and commercialize detalimogene, or if we experience delays as a result of any of the above factors or otherwise, our business would be materially harmed. 26 We expect to make significant investments in our continued research and development of detalimogene and other new product candidates and genetic medicines and services we may develop, which may not be successful, and if they are not successful, we may not be able to achieve or sustain profitability in the future. As an organization, we do not have experience in any such new lines of business, and failure to identify other product candidates and/or execute on the expansion of our business would adversely affect our business and results of operations. Biotechnology product development is expensive, takes years to complete, and has uncertain outcomes. Failure can occur at any stage of product development. In addition, if we determine that any of our current or future products or services are unlikely to succeed, we may abandon them without any return on our investment. We expect to incur significant expenses to advance our genetic medicine development efforts, which may be unsuccessful. Developing new product candidates, such as detalimogene, is a speculative, risky and highly competitive endeavor. Product candidates that initially show promise may fail to achieve the desired results in development and clinical studies and may ultimately not prove to be safe and effective or meet expectations for clinical utility. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. We may need to alter our offerings in development and repeat clinical studies before we develop a potentially successful product. If, after development, a product appears successful, we will still need to obtain FDA and other regulatory approvals before we can market it. The FDAâ€™s approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. The FDA may not clear, authorize or approve any product we develop. Even if we develop a product that receives regulatory clearance, authorization or approval, we would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product may never be commercially successful. Additionally, development of any product or service may be disrupted or made less viable by the development or announcement of competing products or services, which could occur at any time. Because of the numerous risks and uncertainties associated with developing product candidates, we are unable to predict whether or when our therapeutics business may successfully commercialize a product candidate. We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the foreseeable future. We are a clinical-stage biotechnology company and have incurred net losses in each reporting period since our inception, have not generated any revenue from product sales to date and have financed our operations principally through third-party investments in our debt and equity instruments. Our net losses were $55.1 million and $99.9 million for the fiscal years ended October 31, 2024 and October 31, 2023, respectively. As of October 31, 2024, we had an accumulated deficit of $254.7 million. Our lead product candidate, detalimogene, is in clinical trials. Our other programs are in preclinical research. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the pace of our development activities and the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our Common Shares. The estimates of market sizes and forecasts of market growth for the potential demand of our detalimogene and any other product candidates we develop, as provided in this Annual Report and our other public filings and press releases are based on a number of assumptions and may prove to be inaccurate. The actual market may be smaller than we believe, which would adversely affect our business and results of operations. We estimate total addressable markets and forecasts of market growth for detalimogene and any other product candidates we develop. Our estimates, forecasts and key performance indicators are based on a number of complex assumptions, internal and third-party estimates in published literature, and other business data, including assumptions and estimates relating to our ability to manage operating expenses of, invest in, and develop and generate revenue from detalimogene or any other product candidates we develop in the future. While we believe our assumptions and the data underlying our estimates and key performance indicators are reasonable, there are inherent challenges in measuring or forecasting such information. As a result, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors and metrics. Consequently, our estimates of the total addressable markets and our forecasts of market growth may prove to be incorrect. For example, if the annual total addressable markets or the potential market growth is smaller than we have estimated or if the key business metrics we utilize to forecast commercial opportunities are inaccurate, it may have an adverse effect on our business, financial condition, results of operations and prospects. 27 We identified material weaknesses in our internal control over financial reporting and our management has determined that our current internal control over financial reporting is not effective. If we are unable to remedy these material weaknesses, or if we fail to establish and maintain effective internal controls, we may be unable to produce timely and accurate financial statements, and we may continue to determine that our internal control over financial reporting is not effective, which could adversely impact our investorsâ€™ confidence and the price of our Common Shares. Until October 31, 2023, we had been a private company with limited accounting personnel and other resources with which to address internal control over financial reporting. In connection with the preparation and the audit of the consolidated financial statements as of and for the years ended October 31, 2023 and 2022, material weaknesses were identified, as defined under the Securities Exchange Act of 1934, as amended (the â€œExchange Actâ€) and by the Public Company Accounting Oversight Board (United States), in our internal control over financial reporting. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses identified related to: (1) lack of formal policies, procedures and controls related to the design of internal controls over financial reporting including risk assessment process and control activities for certain key financial reporting processes;â€¯ (2) lack of sufficient accounting and financial reporting personnel to perform appropriate accounting analysis and review procedures; (3) lack of personnel with requisite knowledge and experience in the application of U.S. generally accepted accounting principles (â€œU.S. GAAPâ€); (4) general information technology controls that were not designed appropriately (related to access and system changes); and (5) lack of appropriate segregation of duties in the preparation and review of account reconciliations and journal entries. As of October 31, 2024, we have fully remediated material weaknesses 2 and 3 described above, however remediation efforts for material weaknesses 1, 4 and 5 remain ongoing. Accordingly, as of October 31, 2024, our management has concluded that our internal control over financial reporting is not effective. If we are unable to successfully remediate material weaknesses 1, 4 and 5, or if additional material weaknesses are identified, our management may continue to determine that our internal control over financial reporting is not effective, which could adversely impact our investorâ€™s confidence, our ability to raise additional capital, and the price of our Common Shares. The process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. For example, to maintain and improve the effectiveness of our financial reporting, we have committed significant resources, implemented and strengthened existing reporting processes, trained personnel and provided additional management oversight. We will continue to incur additional costs to remediate these weaknesses, primarily personnel costs and external consulting fees. We cannot assure you that any measures we have taken or may take in the future will be sufficient to remediate identified and outstanding material weaknesses, or to avoid potential future material weaknesses. Our management has performed an evaluation of our internal controls over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, however, an independent registered public accounting firm has never performed an evaluation because no such evaluation is currently required. Had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to the Nasdaq listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result. We also could become subject to investigations by the Nasdaq, the SEC or other regulatory authorities. See â€œItem 9A. Controls and Proceduresâ€”Remediation Efforts to Address Material Weaknessâ€ of this Annual Report for information related to material weakness remediation and mitigation. To date, we have not generated any product revenue, have a history of losses and will need to raise additional capital to fund our operations. If we fail to obtain necessary financing, we will not be able to complete the development and commercialization of detalimogene or our other product candidates. The development of biopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, capital-intensive and uncertain process. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to conduct further research and development and preclinical or nonclinical testing and studies and clinical trials of our current and future programs, to seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval. As of October 31, 2024, we had $173.0 million in cash and cash equivalents and $124.9 million in marketable securities. Although we have a detailed current operating plan, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect. We will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for product development and any approved marketing and commercialization activities. Our funding requirements, both near- and long-term, as well as the timing and amount of our operating expenditures, will depend largely on: â€¢the initiation, progress, scope, timing, costs and results of preclinical or nonclinical testing and studies and clinical trials for our product candidates; 28 â€¢the clinical development plans we establish for these product candidates; â€¢the number and characteristics of product candidates that we develop or may in-license; â€¢the terms of any collaboration agreements we may choose to execute; â€¢the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable regulatory authorities outside of the United States; â€¢the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; â€¢the cost of resolving intellectual property disputes, including any patent infringement actions that may be brought by third parties in the future against us or our product candidates; â€¢the effect of competing technological and market developments; â€¢the cost and timing of formulation development and manufacturing of our product candidates, including the completion of commercial-scale outsourced manufacturing activities; â€¢the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or with a partner; and â€¢the costs related to any domestic and/or international expansion. We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty revenues, sales or monetization of future revenue streams, marketing or distribution arrangements or other strategic transactions. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our shareholdersâ€™ rights. Further, to the extent that we raise additional capital through the sale of our Common Shares or securities convertible or exchangeable into our Common Shares, your ownership interest will be diluted. We are party to the Amended Loan Agreement (as defined herein) with Hercules Capital, Inc.

(â€œHerculesâ€ or the â€œLenderâ€), as agent and lender, and several financial institutions. The Amended Loan Agreement subjects us to fixed payment obligations covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For additional information, see â€œItem 7. Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€”Hercules Loan Agreementâ€ and â€œNotes to the Financial Statementsâ€”Note 19, Subsequent Eventsâ€ for additional information on the Hercules Loan Agreement. If we raise additional capital through debt financing, we may be subject to similar or more restrictive conditions than the conditions of the Amended Loan Agreement. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, licensing arrangements, royalty revenues, sales or monetization of future revenue streams, or strategic transactions with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research or development initiatives. Any of the above events could significantly harm our business, financial condition, results of operations and prospects and cause the price of our common shares to decline. We face significant competition from other entities, including biotechnology and pharmaceutical companies, which may result in our competitors discovering, developing or commercializing products before us or more successfully than we do. Our business and results of operations could be adversely affected if we fail to compete effectively. The biotechnology and pharmaceutical industries, including the development of non-viral genetic medicines for administration into mucosal tissues as well as the development of novel therapies for bladder cancer and non-muscle invasive bladder cancer, or â€œNMIBC,â€ specifically, are characterized by rapid growth, a dynamic landscape of competitive product candidates and a strong reliance on intellectual property. We face competition from a variety of organizations, including larger pharmaceutical companies, specialty biotechnology companies, specialty medical device companies, academic research institutions, governmental agencies, as well as public and private institutions. There are several companies that are currently developing gene-based therapeutics for use in a variety of indications, from cancer (including bladder cancer and NMIBC specifically) to rare disease, to regenerative medicine. There are also companies and institutions developing non-gene based therapies such as, but not limited to, drug/device combinations that may be effective in the clinical indications we choose to pursue and oncology drugs. DDX is our proprietary carrier for genetic medicines to mucosal tissues and is the foundation for our nanoparticle formulations. We developed DDX and our patented non-viral genetic medicines to penetrate mucus barriers and to deliver genes to mucosal epithelial cells in a way that is re-dosable, scalable, and designed to integrate into existing clinical practice. Our genetic medicine platformâ€™s leading program, detalimogene, is in the area of immuno-oncology. We believe that a significant number of products are currently 29 under development, and may become commercially available in the future, for the treatment of indications for which we are developing detalimogene, including NMIBC. Competitors using genetic medicines for mucosal tissues include CG Oncology, Inc. and Ferring Pharmaceuticals Inc, both of which are developing products that will compete directly with detalimogene, if approved. More generally, if detalimogene or any future product candidates that we develop are approved, they will compete with surgery, radiation, and drug therapy, including chemotherapy, BCG, hormone therapy, biologic therapy, such as monoclonal and bispecific antibodies, antibody-drug conjugates, radiopharmaceuticals, immunotherapy, cell-based therapy, and targeted therapy, or a combination of any such methods, either approved or under development, which are intended to treat the same indications that we are targeting or may target, including through approaches that may prove to be more effective, have fewer side effects, be less costly to manufacture, be more convenient to administer or have other advantages over detalimogene and any future product candidates that we develop. To the extent Merck or another manufacturer increases the supply of BCG, there may be less demand for alternative treatments such as detalimogene, if approved, in earlier lines of treatment for NMIBC. There are numerous companies that have commercialized or are developing treatments for NMIBC that detalimogene will compete with, if approved, including Bristol Meyers Squibb, Gilead Sciences, Inc., Hoffman-La Roche AG (Roche), CG Oncology, Inc., Ferring Pharmaceuticals Inc., ImmunityBio Inc., Johnson & Johnson Inc., Merck, Protara Therapeutics, Inc., Pfizer, Inc., Aura Biosciences Inc., and UroGen Pharma, Inc.. In addition, many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for and participation in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, are more shelf-stable or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, if we successfully enter it at all. The key competitive factors affecting the success of all of our programs, including detalimogene, are likely to be their efficacy, safety, convenience and availability of reimbursement. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive, or marketed and sold more effectively than any products we may develop. Competitive products may make detalimogene or any future product candidates we develop obsolete or noncompetitive before we generate sufficient revenue to recover the expense of their development and commercialization. If we are unable to compete effectively, our opportunity to generate revenue from the sale of detalimogene or any future product candidates we may develop, if approved, could be adversely affected. If detalimogene or other product candidates that we may develop are approved for the indications for which we are currently conducting or planning clinical trials, they may compete with other products currently under development. We may not be aware of all competitive or potentially competitive products under development by other market participants, and information relating to such products may not be publicly accessible. Competition with other related products currently under development may include competition for clinical trial sites, patient recruitment and product sales. See â€œItem 1. Businessâ€”Competitionâ€ for additional information. The genetic medicine field is relatively new and evolving rapidly. Because of our limited technical, financial and human resources, we are focusing our research and development efforts on detalimogene, as well as further development of our genetic medicine platform and other product candidates we may develop. As a result, we may forego or delay pursuit of other genetic medicine technologies or other therapeutic product candidates that provide significant advantages over our platform or product candidates, which could materially harm our business and results of operations. Genetic medicine is an emerging field of product development with only a small number of genetic medicines having received FDA or EMA approval to date. Our genetic medicine research programs are still at an early stage, and there remain several areas of product development risk, which pose particular uncertainty for our programs given the relatively limited development history of, and our limited prior experience with, genetic medicines. Translational science, manufacturing materials and processes, safety concerns, regulatory pathway and clinical trial design and execution all pose particular risk to our product development activities. Furthermore, the medical communityâ€™s understanding of the causes of many diseases continues to evolve and further research may change the medical communityâ€™s views on what therapies and approaches are most effective for addressing certain diseases. As an organization, we have limited experience conducting IND-enabling studies or clinical trials, including later stage or pivotal clinical trials. In pursuing our new technologies, we have begun to establish our own genetic medicine technical capabilities, but we will need to continue to expand those capabilities by either hiring internally or seeking assistance from outside service providers. Genetic medicine is an area of significant investment by biotechnology and pharmaceutical companies and there may be a scarcity of talent available to us in these areas. If we are not able to expand our genetic medicine capabilities, we may not be able to develop in the way we intend or desire any promising product candidates that emerge from our program, including detalimogene, which would limit our prospects for future growth. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of detalimogene or other product candidates that we may develop. We may also rely on third-party vendors or service providers, including CROs, among others who may fail to meet their commitments to us or deliver their products to us. We may 30 also be forced to rely on a single such provider with no redundancy or alternative. Failure to commence or complete, or delays in our clinical trials, could prevent us from or delay us in commercializing detalimogene or other product candidates that we may develop. Because we have limited financial and managerial resources, we focus on research programs and on genetic medicine technologies and product candidates that we identify for specific indications among many potential options, such as detalimogene in high-risk BCG-unresponsive NMBIC with CIS or other NMIBC indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential, or we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. For example, in June 2024, we announced that, as a result of our prioritization of exploring potential bladder cancer indications for detalimogene, we deprioritized preclinical development of another product candidate, EG-i08 for cystic fibrosis. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Failure to pursue opportunities with greater commercial potential or relinquishing valuable rights to product candidates may have a material adverse effect on our business, financial condition, results of operations and prospects. Detalimogene and our genetic medicine platform are based on novel technologies that are unproven, which makes it difficult to predict the time and cost of development and the probability or timing of subsequently obtaining regulatory approval. We have concentrated our research and development efforts on our genetic medicine platform, and our future success depends on the successful development and maintenance of our platform. However, the technologies that comprise our platform and detalimogene are new and largely unproven. These technologies have been neither extensively studied nor extensively clinically tested, and the scientific and clinical evidence to support the feasibility of developing product candidates based on those technologies in pursuit of regulatory approval and potential commercial viability and success may be considered preliminary and limited. Successful development of product candidates by us will require solving several issues, including proving the safety and efficacy of detalimogene for BCG-unresponsive NMIBC and expanding our mucosal tissue delivery system to treat patient tissues beyond the bladder, such as urogenital and gastrointestinal mucosal tissues. There can be no assurance we will be successful in solving any or all of these issues. We have concentrated our research efforts to date on developing the components of our genetic medicine platform, and our future success is highly dependent on the successful development of our proprietary carrier for genetic medicines to mucosal tissues, therapeutic applications of such technology and the advancement of additional programs focused on diseases of the urogenital and gastrointestinal mucosal tissues. We may decide to alter or abandon our initial programs as new data become available and we gain experience in developing our therapeutics. We cannot be sure that our technologies will yield satisfactory products that are safe and effective, scalable or profitable in any indication we pursue. There can be no assurance that any development problems we experience in the future related to our genetic medicine platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing sustainable, reproducible and scalable manufacturing processes or transferring such processes to any commercial partners, which may prevent us from initiating or conducting clinical trials or commercializing our products on a timely or profitable basis, if at all. We may also fail to build redundancy in these manufacturing processes, such that we will be vulnerable to third-party provider failures that may impair the supply of or manufacture of critical materials, products, or reagents. In addition, the clinical trial requirements of the FDA, the EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. FDAâ€™s regulatory guidance documents, including those that may be applicable to our programs, may change, be cancelled or evolve. Only a small number of genetic medicines have successfully reached the clinical trial phase of development or beyond, limiting insight into the regulatory review process for this field of genetic medicine. As a result, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals in either the United States or the European Union for any product candidates we may develop or how long it will take to commercialize any product candidate that receives marketing approval. Development of new therapeutics involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs, fail to replicate the positive results from our earlier preclinical or clinical studies of our product candidates in later preclinical studies or clinical trials or experience delays in completing or ultimately be unable to complete, the development and commercialization of any product candidates, including, but not limited to, detalimogene. To obtain the requisite regulatory approvals to commercialize detalimogene or any other product candidate that we may develop, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective. Our product candidates are in preclinical development and clinical trial stages and thus their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical studies that support our filed and planned INDs in the United 31 States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support the further development of our product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including detalimogene, we must conduct extensive clinical trials to demonstrate the safety and efficacy of any of these product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during, or even after, the clinical trial process and our ongoing and future clinical results may not be successful. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful and a clinical trial can fail at any stage of testing. Similarly, if regulatory authorities agree, implicitly or explicitly, that a certain set of clinical endpoints is clinically meaningful or adequate to demonstrate safety and efficacy, they may change their determination at a later date. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials and interim results of a clinical trial do not necessarily predict final results. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA and similar marketing applications to other regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We do not know whether any of our clinical trials will be completed on schedule, if at all. We may experience delays in initiating or completing clinical trials and preclinical studies. We also may experience numerous unforeseen events during, or as a result of, any ongoing and future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including that: â€¢we may be unable to generate sufficient preclinical, toxicology, in vivo, in vitro, or other data to support the initiation of clinical trials; â€¢we may experience delays in our discussions with the FDA and other regulatory authorities regarding trial design or other aspects of our trial and study; â€¢regulators or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; â€¢we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; â€¢positive results from our preclinical studies of our product candidates may not necessarily be predictive of the results from required later preclinical studies and clinical trials and positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results; â€¢clinical trials of any product candidates may fail to show safety or efficacy, or produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs; â€¢the number of patients required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate; â€¢the FDA or other regulatory authorities may require us to enroll additional patients in clinical trials than we had planned, including if they determine that patients we have enrolled did not meet the eligibility criteria for the clinical trial or, in the case of detalimogene for BCG-unresponsive NMIBC with CIS, did not meet the requirements of the FDAâ€™s 2018 Guidance Document entitled â€œBacillus Calmette-GuÃ©rin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment Guidance for Industryâ€ (the â€œGuidance Documentâ€); â€¢we may need to add new or additional clinical trial sites; and â€¢our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial. We could also encounter delays if a clinical trial is suspended, placed on clinical hold or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or other regulatory authorities or recommended for suspension or termination by the Data Safety Monitoring Board, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the 32 clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. Our product development costs will increase if we experience delays in clinical testing or marketing approvals, which will correspondingly increase our operating costs. Our preclinical studies or clinical trials may not begin as planned, may need to be restructured or may not be completed on schedule, or at all. Significant preclinical studies or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our preclinical or clinical development programs may harm our business, financial condition, results of operations and prospects. Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time will change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim top-line or preliminary results from our clinical trials. For example, in September 2024, we announced preliminary data from the pivotal cohort of the LEGEND study of detalimogene in high-risk BCG-unresponsive, NMIBC patients with CIS. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we have previously published. As a result, interim and preliminary data should be expected to change as additional patient data become available and as such new data and/or existing data is audited and verified; all data should be viewed with caution until the final data is available. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common shares to fluctuate significantly. In addition, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program (for example, detalimogene), the approvability or commercialization of the particular product candidate or product, and our Company in general. Moreover, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions we reached, our ability to obtain approval for, and commercialize detalimogene and any future product candidates we develop may be harmed, which could harm our business, financial condition, results of operations and prospects. If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We have from time to time experienced and may in the future experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including: â€¢the availability of a sizeable population of eligible patients; â€¢the proximity of patients to study sites; â€¢the design of the trial; â€¢our ability to recruit clinical trial investigators with the appropriate competencies and experience; â€¢competing clinical trials for similar therapies or other new therapeutics; â€¢cliniciansâ€™ and patientsâ€™ perceptions as to the potential advantages and side effects of our product candidate being studied in relation to other available therapies or surgical procedures; â€¢our ability to obtain and maintain patient consents; 33 â€¢the failure of patients to complete a clinical trial; â€¢the availability of approved therapies that are similar in mechanism to our product candidates; â€¢the cost to, or lack of adequate compensation for, prospective patients; and â€¢the risk that patients enrolled in clinical trials will not complete such trials for any reason, including due to health crises, including pandemics, geopolitical conflicts, acts of terrorism, and/or â€œacts of Godâ€ that affect our contract development and manufacturing organizations (â€œCDMOsâ€), suppliers, clinical investigator sites and governing regulatory bodies. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which would reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. Although we have conducted the Phase 1 portion of the LEGEND clinical study of detalimogene, we have not as an organization completed later-stage or pivotal clinical trials or submitted a BLA, and we may be unable to do so for detalimogene or any future product candidates in a timely manner or at all. We will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market detalimogene or any future product candidates we develop. Carrying out pivotal and later-stage clinical trials and the submission of a successful BLA or other comparable foreign regulatory submission are complicated processes. As an organization, we have conducted the Phase 1 portion of the combined Phase 1/2, open-label study of detalimogene referred to as the â€œLEGENDâ€ study and are conducting the Phase 2 multi-cohort portion of the LEGEND study consisting of three cohorts, including the pivotal cohort evaluating detalimogene in patients with BCG-unresponsive NMIBC with CIS. We have not yet completed any later-stage or pivotal clinical trials for detalimogene or any other product candidate. We also have limited experience as a company in preparing and submitting marketing applications and have not previously submitted a BLA or other comparable foreign regulatory submission for any product candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many additional clinical trials of detalimogene or any other product candidates we develop will be required or how such additional trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of a BLA and regulatory approval of detalimogene or any of the other product candidates we develop. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of detalimogene or any of other product candidates we develop. Failure to commence or complete, or delays in, our ongoing or future clinical trials could prevent us from or delay us in submitting BLAs or other comparable foreign regulatory submissions for and commercializing detalimogene or any of other product candidates we develop. Use of our novel genetic medicine platform, detalimogene and other therapeutic product candidates we may develop could result in or be associated with harmful side effects, adverse events or other safety risks, which could cause us to delay, suspend or discontinue their clinical trials and/or development or abandon them, delay or prevent their regulatory approval, limit their commercial potential, if approved, or result in other significant negative consequences (including voluntary corrective actions or agency enforcement actions) that could severely harm our business and results of operations. In addition, these harmful side effects, adverse events or other safety risks may not be appropriately recognized or managed by our treating staff, which could result in litigation and reputational damage. Detalimogene and other product candidates we may develop may be associated with harmful side effects, adverse events or other safety risks. Results of clinical trials could reveal severe or recurring side effects, toxicities or unexpected events, including death. There may also be delayed adverse events that may not be appropriately recognized or managed by our treating staff, which could result in litigation and reputational damage. We expect to have to train medical personnel using detalimogene or any other product candidates we may develop to understand the side effect profiles for our clinical trials and upon any commercialization of such product candidates. Inadequate training in recognizing or managing the potential side effects of such product candidates could result in patient injury or death. If any such events occur, clinical trials or commercial distribution of detalimogene or any other product candidates or products we develop could be suspended or terminated, and our business and reputation may be substantially harmed. Treatment-related side effects could affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, deny approval of or require us to cease selling detalimogene or any other product candidates or products we develop for any or all targeted indications. If we elect, or are required, to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenues from them or other product candidates that we develop may be delayed or eliminated. 34 Additionally, if we successfully develop detalimogene or any other product candidate and it receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy (â€œREMSâ€) to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we and others later identify undesirable side effects caused by any product that we develop. Such identification could also have several additional significant negative consequences, such as: â€¢regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution; â€¢regulatory authorities may require additional warnings on the label, including â€œboxedâ€ warnings, or issue safety alerts, â€œDear Healthcare Providerâ€ letters, press releases or other communications containing warnings or other safety information about the product; â€¢we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; â€¢we may be required to change the way a product is administered or conduct additional trials; â€¢the product may become less competitive; â€¢we may decide to remove the product from the marketplace; â€¢we may be subject to fines, injunctions or the imposition of civil or criminal penalties; â€¢we could be sued and be held liable for harm caused to patients; and â€¢our reputation could be harmed. â€¢Any of these events could prevent us from achieving or maintaining market acceptance of any potential product. Even if detalimogene or any other therapeutic product candidates that we develop receives regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors (including government health administration authorities and private health insurers) and others in the medical community necessary for commercial success, in which case we may not generate significant revenues and become profitable, which could adversely affect our ability to conduct our business and our results of operations. The commercial success of detalimogene or any other product candidates that we develop will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Even if detalimogene or any other product candidates developed by us receives regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of detalimogene and any other product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including: â€¢the wider acceptance by patients of products derived from or involving RNA or DNA manufacturing processes; â€¢the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials published in peer-reviewed journals or otherwise made available to the public (e.g., through FDA advisory committee meetings); â€¢the potential and perceived advantages compared to alternative treatments; â€¢the ability to offer our products for sale at competitive prices and to obtain coverage by third-party payors; â€¢the ability to offer appropriate patient access programs, such as co-pay assistance; â€¢the extent to which physicians recommend our products to their patients; â€¢convenience and ease of handling, dosing and administration compared to alternative treatments; â€¢the clinical indications for which the product candidate is approved by the FDA, EMA or other comparable non-U.S. regulatory agencies; â€¢product labeling or product insert requirements of the FDA, EMA or other comparable non-U.S. regulatory authorities, including any limitations, contraindications or warnings contained in a productâ€™s approved labeling; â€¢restrictions on how the product is distributed; â€¢the timing of market introduction of competitive products; â€¢publicity concerning our products or competing products and treatments; â€¢the effectiveness of marketing and distribution efforts by us and other licenses and distributors; â€¢shortages or lack thereof of competitive or potentially competitive products, or products utilized in the standard-of-care for our patients, such as BCG; 35 â€¢sufficient governmental third-party coverage or reimbursement; and â€¢the prevalence and severity of any side effects. If detalimogene or any other product candidate developed by us does not achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue and may not become or remain profitable. The failure of detalimogene or any other product candidates we develop to find market acceptance could harm our business, financial condition, results of operations and prospects. Independent of any actions taken by us, negative developments in the field of genetic medicine, intravesical or NMIBC therapeutic development could damage public perception of detalimogene and any other product candidates that we develop, which could adversely affect our ability to conduct our business and our results of operations, or to obtain and retain regulatory approvals for such product candidates. Our novel genetic medicine platform and detalimogene are comprised of new and largely unproven technologies, with no gene therapeutic product candidates approved to date. Gene therapeutics may not gain the acceptance of the public or the medical community and/or they may not gain the acceptance of the public or medical community within our indications of interest or development areas. To date, several other efforts to leverage genetic medicine technologies have generally demonstrated an inability to generate predictable results or to manufacture products at suitable scale to treat more than a small number of patients. Our success will depend on our ability to demonstrate that our genetic medicine platform, detalimogene and any other product candidates we develop and related services can overcome these challenges. If detalimogene or any other product candidate that we develop s is unable to successfully treat the intended organ or lesion and establish proof of concept in a certain disease, it may indicate that we will not be able to apply our genetic medicine platform to other diseases affecting the intended tissue area or other areas. This may also indicate a decrease in the probability of our success for other targets using the same modality in the same or different cell types, as well as our engineered approach and delivery approach, more generally. Such failures could negatively affect the public or medical communityâ€™s perception of our genetic medicine platform and gene therapeutics in general. Additionally, our success will depend upon physicians who specialize in the treatment of diseases targeted by detalimogene or any other product candidates that we develop, if approved, prescribing treatments that involve the use of those product candidates, if approved, in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of detalimogene or any other product candidates that we develop or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of gene therapeutics, could result in a decrease in demand for detalimogene, if approved, or any other product that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of, or modification to, our clinical trials. Any future negative developments in the field of genetic medicine could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for detalimogene or any other product candidates that we develop. We may not be successful in our efforts to utilize our novel genetic medicine platform to identify and develop additional product candidates. Due to our limited technical, financial and human resources and access to capital, we may choose to prioritize development of certain product candidates, such as our initial focus on developing detalimogene, which may prove to be the wrong choice and may adversely affect our business and results of operations. An important element of our strategy is utilizing our genetic medicine platform to generate multiple product candidates. Although we intend to develop numerous product candidates targeting various cell types and indications and carrying different biologically active drug molecules, in addition to detalimogene, we may fail to identify viable new product candidates for clinical development for a number of reasons. For example, while we believe our genetic therapy platform is capable of transfecting many different tissue types with varied genetic cargos, such as nucleic acid therapeutics (e.g., DNA), antisense oligonucleotides, siRNA, miRNA, mRNA, genetic medicine and gene editing mechanisms, we have not yet successfully advanced any proprietary enGene-developed drug candidate incorporating these cargoes into clinical trials beyond detalimogene, and we may not be successful in developing products to effectively employ these types of cargoes or molecules. If we fail to identify additional potential product candidates, our business could be materially harmed. Research programs to pursue the development of our product candidates and using our genetic medicine platform to design and identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our genetic medicine platform and research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including: â€¢the research methodology used may not be successful in identifying potential indications and/or product candidates; 36 â€¢potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs, or that make the product candidates impracticable to manufacture, unmarketable or unlikely to receive marketing approval; or â€¢it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio. If any of these events occur, we may be forced to abandon our research or development efforts for a program or programs, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful, which would be costly and time-consuming. Our use of third parties to manufacture, develop and test our therapeutic product candidates for preclinical studies and clinical trials increases the risk that we will not have sufficient quantities of our product candidates or products, or necessary quantities of such materials on time or at an acceptable cost. We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture drug supplies for our ongoing clinical trials or any future clinical trials that we may conduct, and we lack the resources to internally manufacture detalimogene or any other product candidates we develop on a commercial scale. We rely, and expect to continue to rely, on third-party manufacturers to produce detalimogene or other product candidates that we may identify for clinical trials, as well as for commercial manufacture if detalimogene or any other product candidates we develop receive marketing authorization and approval. We rely entirely on numerous third-party suppliers to provide us with various product components. We may not have alternative suppliers for certain of these product components. Any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer or testing laboratory could considerably delay the clinical development and potential regulatory authorization and commercial launch of such product candidate, which could harm our business, financial condition, results of operations and prospects. We currently do not have relationships with alternate third-party contract manufacturers and testing laboratories for our critical raw materials and product candidates that could sustain our operations in the event we experience a disruption of service from our existing third-party contract manufacturers and testing laboratories. As a result, we are materially reliant on our existing contract manufacturers and testing laboratories and susceptible to material operational disruptions due to factors that may be unknown to us and unforeseeable. Our providers may also materially change the terms of our commercial arrangements for any reason or no reason, which could adversely affect our materials costs, ability to manufacture the drug at a sustainable cost, and profit margin on any sales. We may be unable to identify and appropriately qualify third-party manufacturers and testing laboratories or establish agreements with third-party manufacturers and testing laboratories or do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers and testing laboratories, reliance on third-party manufacturers entails additional risks, including: â€¢reliance on the third-party for sourcing of raw materials, components, testing and such other goods as may be required for execution party of our overall manufacturing process; â€¢risk of single sourced critical raw materials, drug substance and drug product, where secondary back-up vendors are not yet available; â€¢risk of increased and/or extended lead times for critical raw materials, reagents and equipment, thus requiring significant investment in building adequate inventory to avoid significant disruptions to manufacturing processes; â€¢reliance on third-party to ensure availability of adequate manufacturing capacity to meet product demand based on the needs of their other clients; â€¢reliance on the third-party for regulatory compliance and quality assurance for the manufacturing and/or testing activities each performs; â€¢reliance on third-party to adequately validate processes for timely approval of the BLA required for commercialization of product; â€¢the possible breach of the manufacturing and/or testing agreement by the third-party; â€¢the possible misappropriation of proprietary information, including trade secrets and know-how; and the possible termination or non-renewal of the agreement by the third-party at a time that is costly or inconvenient for us. Furthermore, our contract manufacturing organizations (â€œCMOsâ€) and testing laboratories are engaged with other companies to supply and/or manufacture and/or test materials or products, which exposes our manufacturers and testing laboratories to regulatory risks for the production and testing of such materials and products. The facilities used by our CMOs to manufacture and/or test detalimogene or any other product candidates we develop are subject to review by the FDA and other non-U.S. authorities pursuant to 37 inspections that will be conducted after we submit a BLA, or other marketing application to the FDA and other non-U.S. authorities. We do not directly conduct the manufacturing and testing of any material or products. Therefore, we are materially dependent on our CMO partners and contract testing laboratories to operate in compliance with the regulatory requirements, known as current good manufacturing practice (â€œcGMPâ€) requirements for manufacture of drug and device products or similar requirements outside the United States. If our CMOs and contract testing laboratories cannot successfully manufacture and/or test material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure or maintain regulatory authorization for detalimogene or any other product candidates we develop that are manufactured at these manufacturing facilities, resulting in delay or failure in the clinical development and commercialization of our products, which would have a material adverse effect on us. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or another non-U.S. regulatory agency does not approve these facilities for the manufacture and/or testing of detalimogene or any other product candidates we develop, if any agency withdraws its approval in the future, or if we identify material gaps in quality control and compliance at our selected CMOs, we may need to find alternative manufacturing facilities, which would negatively impact our ability to develop and deliver our products to markets around the world could delay product supply to patients in clinical studies or to commercial customers for any approved products, and may increase the overall cost of manufacturing our products. Detalimogene or any other product candidates we develop may compete with other product candidates and marketed products for access to manufacturing and/or testing facilities. Any performance failure on the part of our existing or future CMOs could delay clinical development, marketing approval or commercialization. Our current and anticipated future dependence upon others for the manufacturing of detalimogene or any other product candidates we develop may adversely affect our future profit margins and our ability to commercialize detalimogene or any other product candidates we develop that receive marketing approval on a timely and competitive basis. Detalimogene is complex to manufacture, and the manufacturing process for any other product candidates we develop may be similarly complex or more complex, and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of our third-party manufacturers with whom we contract encounter these types of difficulties, our ability to supply detalimogene or any other product candidates we develop for clinical trials or as products for patients, if approved, could be constrained, delayed or stopped, or we may be unable to maintain a commercially viable cost structure. The manufacturing processes used to produce detalimogene are complex and novel and have not been validated for clinical or commercial production. The manufacturing processes used to produce any future product candidates that we develop may be similarly or more complex and novel. As a result of these complexities, the cost to manufacture our product candidates is generally higher than traditional biopharmaceutical compounds and the manufacturing processes may prove to be less reliable and may be more difficult to reproduce. For example, for detalimogene we must separately manufacture a novel plasmid DNA drug substance (DS), a novel co-polymer excipient (DDX) and a novel block co-polymer excipient (PEG-b-PLE). We then combine those ingredients in the drug product manufacturing process. There are many points throughout this process, and the manufacturing processes of other product candidates we develop, that can lead to failure. Failure in the production of any of our product components or candidates could have a material adverse effect on our business, financial condition, results of operations and prospects. Some examples of manufacturing challenges and potential failure we may encounter follow: â€¢As part of the manufacturing process of DS, bacterial cells are inoculated to a fermenter and expanded. â€¢These bacteria produce the plasmid DNA DS, which is purified from the cells by an extensive purification process. At any stage, any or all of these processes can fail, including the biological or purification processes, which would result in batch failure. These processes can fail due to contamination, inadequate purification or other reasons. â€¢The manufacture of DDX and PEG-b-PLE involves multiple complex chemical synthesis and purification steps to produce final products with target specifications and yield. At any stage, any or all of these processes can fail, including the chemical or purification processes. â€¢The manufacture of detalimogene requires careful and complex combination of DS with DDX and PEG-b-PLE followed by sterile filtration, filling and lyophilization to yield the drug product. At any stage, any or all of the processes involved can fail, including the mixing, sterilization, filling, lyophilization or storage processes. Our manufacturing processes are also susceptible to product loss or failure due to logistical issues associated with multiple outsourced activities across the range of manufacturing, shipping of materials to analytical laboratories, cold chain distribution to where products will be administered to patients, interruptions in the manufacturing processes, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability of product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral or other contaminations are discovered in detalimogene or other product candidates we develop or in the manufacturing facilities in which detalimogene or those other product candidates are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could result in our inability to timely produce or ship product. Further, as product candidates are developed through preclinical to later-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as 38 manufacturing methods, are altered in an effort to optimize processes and results. If we make these types of changes, we may not achieve our intended objectives, and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials. Although we continue to optimize our manufacturing processes, doing so is difficult and uncertain. There are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among other things, cost overruns, production delays, potential problems with process scale-out, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. If we are unable to adequately validate or scale-up our manufacturing processes with our current manufacturing partners, we will need to transfer such processes to another manufacturing partner and complete the manufacturing validation process, which can be a lengthy process. We ultimately may not be successful completing the transfer of our manufacturing processes to one or more of the manufacturers on whom we rely. The manufacturers who become responsible for our processes may not have the necessary capabilities to complete the implementation and development processes to our specifications or standards. If we are able to adequately validate and scale-up a particular manufacturing process for detalimogene and other product candidates we develop with a contract manufacturer, we will still need to negotiate an agreement for commercial supply with that contract manufacturer and it is not certain we will be able to come to agreement on commercially reasonable terms, or at all. As a result, we may ultimately be unable to manage the cost of goods for detalimogene or other product candidates we develop to levels that will allow for an attractive return on investment if and when detalimogene or those other product candidates are approved and commercialized. The manufacturing processes and facilities used for any products that we may develop are subject to the FDA and non-U.S. regulatory authority approval processes, and we will need to contract with manufacturers who we believe can meet applicable FDA and non-U.S. regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or if the facilities used to manufacture our products are found to be non-compliant for any reason, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications and under required good manufacturing practices acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and prospects. Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. In addition, the FDA, the EMA and other non-U.S. regulatory authorities may require us to submit samples of any lot of any approved product, together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other non-U.S. regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in our manufacturing processes, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing processes could restrict our ability to meet market demand for our products. Any problems in our manufacturing processes or facilities at our CMOs, or the perception of the possibility of problems in such processes or facilities, could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. We have no experience in developing a manufacturing facility for our biologic products and may never be successful in developing our own manufacturing facility or capability. We expect to evaluate the possibility of establishing our own capabilities and infrastructure, including a manufacturing facility. If we choose to build our own manufacturing facility, we will need significant funding and will need to select an adequate location. We expect that development of our own manufacturing facility would provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we have no experience in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. If we determine to establish our own manufacturing capabilities and infrastructure, we will also need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development, and eventual commercialization, if approved, of our product candidates. If we fail to select the correct location, 39 complete the construction in an efficient manner, recruit the required personnel and generally manage our growth effectively, the development and production of our product candidates could be curtailed or delayed. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or could prove costly. Even if we are successful, any manufacturing capabilities we develop could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business, financial condition, results of operations and prospects. Changes in the manufacturing or formulation of detalimogene or any other product candidate we develop may result in additional costs or delay, which could adversely affect our business and results of operations. As product candidates are developed through preclinical studies to later-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods or formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause detalimogene or any other product candidates that we develop to perform differently and affect the results of ongoing or planned clinical trials or other future clinical trials conducted with the altered materials. In addition, such changes and any other similar changes in the future may also require additional testing or notification to or approval by the FDA or other regulatory authorities. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of detalimogene or any other product candidates that we develop and/or jeopardize our ability to commence product sales and generate revenue. Detalimogene is, and any other product candidates we develop may be, complex to analyze and we may encounter difficulties in product release testing, particularly with respect to bioassay potency testing. If we or any of our contract testing laboratories encounter difficulties, our ability to provide supply of detalimogene or any other product candidates that we develop for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. The analytical methods used to test detalimogene are complex and many are novel and have not been validated for clinical or commercial production. The manufacturing processes used to produce any future product candidates that we develop may be similarly complex and novel. For example, in addition to several complex physio-chemical tests for detalimogene, drug substance (DS) and novel excipients, we also test detalimogene and the DS for biological potency using multiple unique cell-based assays. We rely on third-party laboratories to develop and conduct these assays. These assays may be subject to inherent variability and limitations such as, but not limited to, variations in assay conditions, reagents, equipment, or interpretation of results that could lead to inconsistent or inaccurate measurements of potency. Inaccurate potency assessments may affect our ability to demonstrate adequate control of the efficacy and safety of our drug product to regulatory authorities, potentially resulting in regulatory delays, additional testing requirements, or even rejection of our product. Furthermore, changes in regulatory guidelines or evolving scientific understanding may necessitate modifications to the biological potency assays, requiring additional validation studies and potential delays in the development or commercialization of detalimogene or any other product candidates we develop. It is important to note that despite our efforts to ensure the accuracy and reliability of these assays, there may be factors beyond our control that could impact their effectiveness, thereby affecting the overall success of our product candidates. Although we continue to optimize our testing methods, doing so is a difficult and uncertain task, and there are risks associated with developing these methods to the level required for advanced clinical trials and commercialization, including, among other things, cost overruns, potential problems with reproducibility, stability issues, consistency and timely availability of reagents or raw materials needed to execute the testing. If we are unable to adequately validate testing methods with our current testing laboratories, we will need to transfer to another laboratory and repeat the analytical validation process, which can be a lengthy process. We ultimately may not be successful in transferring the analytical methods to contract testing laboratories and the selected contract laboratories may not have the necessary capabilities to complete the implementation and validation process for the assays. If we are able to adequately transfer and validate testing methods for detalimogene or any other product candidates we develop with a contract laboratory, we will still need to negotiate a service agreement with that contract laboratory and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to manage the cost of goods for detalimogene or any other product candidates we develop to levels that will allow for an attractive return on investment if and when those product candidates are approved and commercialized. The analytical testing methods for any products that we may develop are subject to the FDA and non-U.S. regulatory authority approval processes, and we will need to contract with laboratories we believe can meet applicable FDA and non-U.S. regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably test products in a manner acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for detalimogene or any other product candidates we develop, there is no assurance that either we or our CMOs will be able to test the approved product in a manner required by good manufacturing practices acceptable to the FDA or other regulatory authorities, to test products with sufficient throughput to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of detalimogene or any other product candidates we develop, impair 40 commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and prospects. Our future success depends on our ability to test our products on a timely basis with acceptable costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we could incur higher testing costs if testing methods or standards change, and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditure. Specifically, because detalimogene or any other product candidates we develop may have a higher testing requirement than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. The market opportunities for detalimogene and any other product candidates we develop may be limited to a small group of patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate. Cancer and other disease therapies are sometimes characterized as first-line, second-line or third-line and the FDA often approves new therapies initially only for third-line use. When cancers are detected they are treated with first-line of therapy with the intention of curing the cancer. This treatment generally consists of chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. If the patientâ€™s cancer relapses, then the patient is given a second-line or third line therapy, which can consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Generally, the later the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations. Initial approvals for new cancer and other disease therapies are often restricted to later lines of therapy for patients with advanced or metastatic disease, limiting the number of patients who may be eligible for such new therapies, which may include our product candidates. Our lead product candidate, detalimogene, is being developed to treat patients with BCG-unresponsive NMIBC. Our projections of both the number of people who have the disease we are targeting, as well as the subset of people with these diseases in a position to receive our therapies, if approved, are based on our beliefs, research and estimates. These estimates have been derived from a variety of sources, including scientific literature, input from key opinion leaders, patient foundations or secondary market research databases and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for detalimogene or any other product candidates we develop may be limited or may not be amenable to treatment with such product candidates. Even if we obtain significant market share for detalimogene or any other product candidates we develop, because certain of the potential target populations may be small, we may never achieve profitability without obtaining regulatory approval for additional indications. If the market opportunities for detalimogene or any other product candidates we may develop are smaller than what we believe they are, our potential revenues may be lower than projected and our business may be harmed. We depend on our executive team and key personnel, and if we do not successfully manage the previously announced transitions of our Chief Executive Officer and other executive officers, or if we lose one or more of our executive officers or key employees or are unable to attract and retain highly skilled employees, such events could harm our business. Our success depends largely upon the continued service of our executive officers. These executive officers are at-will employees and therefore they may terminate employment with us at any time with no advance notice. In February 2024, we announced the planned transition of our former Chief Executive Officer, Jason Hanson. In July 2024, we appointed Ronald Cooper as our new Chief Executive Officer and Mr. Hanson transitioned to a consulting role as Senior Strategic Advisor and we promoted Dr. Raj Pruthi to replace Dr. Richard Bryce as our Chief Medical Officer. In October 2024, we appointed Joan Connolly as Chief Technology Officer and our former Chief Technology Officer, Dr. Anthony Cheung, transitioned to the role of Chief Scientific Officer, succeeding Dr. James Sullivan. Leadership transitions can be difficult to manage and inherently cause some loss of institutional knowledge, which can negatively affect strategy execution and our operation. An inadequate transition has the potential to negatively impact our operations and relationships with employees, investors and other third parties due to increased or unanticipated expenses, operational inefficiencies, uncertainty regarding changes in strategy, decreased employee morale and productivity, increased turnover and increased difficulty attracting and retaining key executives and employees. If we are unable to effectively manage such transitions or if we have any future transition or loss of the services of any of our executives or highly skilled technical and managerial personnel, it could have a disruptive impact on our ability to implement our business strategy and to meet our financial and operational goals, and as a result our strategic plans and financial performance may be adversely impacted. Our success also depends on the skills, experience and performance of members of our senior management team and key personnel. The individual and collective efforts of our senior management team and key personnel are important as we continue to develop product candidates, establish strategic partnerships, build out our operations and prepare for potential regulatory approval and commercialization of detalimogene, if approved. The loss or incapacity of existing members of our executive management team and key personnel could adversely affect our operations if we experience difficulties in hiring qualified successors. If we are not successful in attracting and retaining highly qualified personnel, our business, financial condition, results of operations and prospects may be harmed. 41 Our research and development initiatives, manufacturing processes and business depend on our ability to attract and retain highly skilled scientists and other specialized individuals. We may not be able to attract or retain such qualified scientists and other specialized individuals in the future due to the competition for qualified personnel among life science and technology businesses. Our research and development initiatives, laboratory operations and manufacturing processes depend on our ability to attract and retain highly skilled and experienced scientists, clinical personnel, technicians, engineers, quality-control and manufacturing personnel. We may not be able to attract or retain qualified scientists, clinical personnel, technicians or engineers in the future due to the competition for qualified personnel among life science and technology businesses. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Additionally, we may be unable to identify, hire and retain the experienced scientific, quality-control and manufacturing personnel needed to transfer our manufacturing processes and test methods to CMOs and external testing laboratories. Further, if we endeavor to conduct manufacturing processes internally, we may be unable to identify, hire or retain the personnel needed to conduct our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. We may have difficulties locating, recruiting or retaining qualified personnel across functions that we deem critical to our success. Recruiting, training and retention difficulties can limit our ability to support our research and development and commercialization efforts. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory and commercialization strategy. Our consultants and advisors may provide services to other organizations and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current consultants or advisors might impede the achievement of our research, development, regulatory and commercialization objectives. We cannot assure you that we will be able to adequately address these additional risks. If we are unable to do so, our operations might suffer. We face risks related to epidemics and other outbreaks of communicable diseases which could significantly disrupt our operations, including our clinical trials and preclinical studies, and adversely affect our business and results of operations. Public health crises could have an adverse effect our business. Quarantines, travel restrictions and other public health and safety measures implemented in response to a pandemic could adversely impact our operations, and the ultimate impact is highly uncertain and cannot be predicted with confidence. Effects of a pandemic that may delay or otherwise adversely affect our ongoing and planned preclinical activities, our planned clinical trials as well as our business generally, include: â€¢delays related to disruptions at CROs and contract manufacturers, or in the supply chain; â€¢delays in receiving approval from regulatory authorities to initiate our planned clinical trials; â€¢delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff who, as healthcare providers, may have heightened exposure; â€¢delays or difficulties in enrolling and retaining patients in clinical trials; â€¢delays in clinical sites receiving the supplies and materials needed to conduct our planned clinical trials; â€¢difficulties interpreting data from clinical trials; â€¢diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials; â€¢interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; â€¢interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; and interruptions, difficulties or delays arising in our existing operations and company culture as a result of many of our employees working remotely. Any of these effects, and other effects of a pandemic could have a material adverse effect on our business, financial condition, results of operations and prospects. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States, Canada, and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates. We or the third parties upon whom we depend may be adversely affected by risks beyond our control, such as natural disasters, political crises, acts of terrorism, epidemics and other outbreaks of communicable diseases, war or other catastrophic events and our business continuity and disaster recovery plans may not adequately protect us from the adverse effects of such events. We, our suppliers and third-party service providers are vulnerable to damage from natural disasters, including but not limited to earthquakes, fires or floods, power loss, communications failures, public health crises, such as pandemics and epidemics, political crises, 42 such as terrorism, war, political instability or other conflict and similar events. If any such disaster were to occur, our ability to operate our business at any of our or our third party facilities could be adversely affected. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or other facilities, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. For example, since February 2022, Russian military forces have continued their significant military invasion of Ukraine. Since October 2023, with the launch of the Israel-Hamas war, there has been increased hostilities in the Middle East. The impact to these countries and regions, as well as actions taken by other countries, including new and stricter sanctions by the United States, Canada, the United Kingdom, the European Union and other countries and organizations against certain officials, individuals, regions, and industries in the affected areas, and each countryâ€™s potential response to such sanctions, tensions, and military actions could continue to have a material adverse effect on the global economy and political situation. As of the date of this Annual Report, we (i) are not conducting clinical or nonclinical studies in Ukraine, Belarus, Russia, or the Middle East, (ii) are not relying upon service providers or vendors from any of these regions to advance our product development programs, (iii) do not source biomanufacturing critical raw materials, equipment, or other supplies directly from these regions, and (iv) are not aware nor have we received notification from our supply vendors that the sourcing of any general laboratory or manufacturing materials may be negatively impacted due to such conflict and related sanctions. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business, financial condition, results of operations and prospects. Regulatory Risks Nearly all aspects of our activity and our products and services are subject to extensive regulation by various U.S. federal and state agencies and regulatory bodies in non-U.S. jurisdictions, and compliance with existing or future regulations could result in unanticipated expenses or limit our ability to offer our products and services. Once developed, detalimogene, and any future product candidates developed using our genetic medicine platform will require regulatory approval, which is a lengthy, expensive, and inherently unpredictable process with uncertain outcomes and cost and is subject to the potential for substantial delays. We cannot give any assurance whether or when detalimogene or any other product candidates we develop will receive regulatory approval, which is necessary before they can be commercialized. Regulatory requirements governing gene and cell therapy products, and in particular any novel genetic medicine products we may develop, have changed frequently and may continue to change in the future. We are aware of a limited number of genetic medicine products that have received marketing authorization from the FDA and EMA. Even with respect to more established products in the genetic medicine field, the regulatory landscape is still developing. In 2016, the FDA established the Office of Tissues and Advanced Therapies (â€œOTATâ€) within its Center for Biologics Evaluation and Research to consolidate the review of genetic medicine and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee, among others, to advise this review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products (â€œOTPâ€) and elevation of OTP to a â€œSuper Officeâ€ to meet its growing cell and genetic medicine workload. Genetic medicine clinical trials conducted at institutions that receive funding for recombinant DNA research from the U.S. National Institutes of Health (â€œNIHâ€), also are potentially subject to review by the Office of Biotechnology Activitiesâ€™ Recombinant DNA Advisory Committee (â€œRACâ€); however, the NIH announced that the RAC will only publicly review clinical trials if the trials cannot be evaluated by standard oversight bodies and pose unusual risks. The same applies in the European Union. The EMAâ€™s Committee for Advanced Therapies (â€œCATâ€), is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. The role of CAT is to prepare a draft opinion on an application for marketing authorization for a genetic medicine medicinal candidate that is submitted to the Committee for Medicinal Products for Human Use (â€œCHMPâ€), before CHMP adopts its final opinion. In the European Union, the development and evaluation of a genetic medicine medicinal product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for genetic medicine medicinal products and require that we comply with these new guidelines. As a result, the procedures and standards applied to genetic medicine products and cell therapy products may be applied to any product candidates we may develop, but that remains uncertain at this point. These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and 43 interpretations, delay or prevent approval and commercialization of detalimogene and any other product candidates we may develop, or lead to significant post-approval limitations or restrictions. As we advance detalimogene and any other product candidates we may develop, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of these product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business. Although the FDA decides whether individual genetic medicine protocols may proceed, the RAC public review process, if undertaken, can delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Conversely, the FDA can put an IND on a clinical hold even if the RAC has provided a favorable review or an exemption from in-depth, public review. If we were to engage an NIH-funded institution to conduct a clinical trial, now or in the future, that institutionâ€™s institutional biosafety committee, as well as its IRB would need to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of genetic medicine products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of detalimogene or any other product candidates we may develop. Similarly, the EMA may issue new guidelines concerning the development and marketing authorization for genetic medicine products and require that we comply with these new guidelines. As we are initially seeking to identify and develop product candidates to treat diseases using novel technologies, there is heightened risk that the FDA, the EMA or other regulatory authority may not consider the clinical trial endpoints that we propose to provide clinically meaningful results. Even if the endpoints are deemed clinically meaningful, we may not achieve these endpoints to a degree of statistical significance, particularly because many of the diseases we are targeting with our platform have small patient populations, making development of large and rigorous clinical trials more difficult. Adverse developments in post-marketing experience or in clinical trials conducted by others of genetic medicine products or products developed or marketed for indications of interest to us, such as NMIBC, may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for development or approval of detalimogene or any other product candidates we may develop or limit the use of products utilizing non-viral genetic medicine technologies, either of which could materially harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as detalimogene or other product candidates we may develop can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing non-viral genetic medicine technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the commercialization of resulting products. In addition, ethical, social and legal concerns about genetic medicine, genetic testing and genetic research could result in additional regulations or prohibiting the processes we may use. Federal and state agencies, congressional committees and non-U.S. governments have expressed their intentions to further regulate biotechnology. More restrictive regulations or claims that detalimogene and any other product candidates we may develop are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of detalimogene and any other product candidates we may develop. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be. As we advance detalimogene and any other product candidates we may develop through clinical development, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of detalimogene and any other product candidates we may develop or lead to significant post-approval limitations or restrictions. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue. We have designed and are currently conducting the clinical trials for detalimogene in accordance with the Guidance Document. This document, which was updated in draft form in August 2024, sets forth guidance for patient selection and describes a potentially abbreviated regulatory path for approval provided certain recruitment, efficacy, and safety data are met. The FDA may review, revoke, or otherwise modify these guidelines at any time, for any reason, which would have a material adverse effect on our approval timelines or process. In addition, the Guidance Document is in draft form subsequent to FDAâ€™s 2024 revisions, and it is possible that some or all of its key provisions may be modified prior to the documentâ€™s finalization. Furthermore, approval of other competitive products treating the same indication may reduce the agencyâ€™s propensity to support abbreviated approval pathways, which could cause our programs to be delayed in achieving regulatory approval or contribute to our failure to achieve approval at all. 44 We cannot predict whether or when we will obtain regulatory approval to commercialize detalimogene or any other product candidate we may develop in the United States or any other jurisdiction and any such approval may be for a narrower indication than we seek. We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate and our application to commercialize it. Even if detalimogene or any other product candidates we may develop meet their safety and efficacy endpoints in clinical trials, regulatory authorities may not complete their review processes in a timely manner or we may not be able to obtain regulatory approval. Additional delays may result if an FDA panel of experts (â€œAdvisory Committeeâ€) or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions, boxed warnings or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of detalimogene or any other product candidates we may develop. Any of the foregoing scenarios could materially harm the commercial prospects for detalimogene or any other product candidates we may develop and materially adversely affect our business, financial condition, results of operations and prospects. If we are not able to obtain or if there are delays in obtaining required regulatory approvals for detalimogene or any other product candidates that we may develop, we will not be able to commercialize or will be delayed in commercializing detalimogene or any other product candidates that we may develop and our ability to generate revenue will be adversely affected. Even if we eventually gain approval for detalimogene or any of other product candidates, we may be unable to commercialize them. Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize detalimogene or any other product candidates that we may develops, we must obtain marketing approval. Detalimogene or any other product candidates that we may develop in the future, require research and development, preclinical studies, nonclinical testing, and clinical trials prior to seeking regulatory approval, and commencing commercial sales. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that neither detalimogene nor any other product candidates we may seek to develop in the future will ever obtain regulatory approval. In certain instances, we may need to rely on third-party CROs and/or regulatory consultants to assist us in this process, and we may have limited control over those third parties and their conduct with respect to our development programs and product candidates. To date, we have focused substantially all of our efforts and financial resources on identifying and developing our product candidates, including conducting lead optimization, nonclinical studies, preclinical studies and clinical trials, and providing general and administrative support for these operations. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidateâ€™s safety, purity, efficacy and potency. Securing regulatory approval also requires the submission of information about the manufacturing processes for the biologic product candidate to, and inspection of manufacturing facilities by, the relevant regulatory authority. Manufacturing facilities must comply with cGMP regulations, which include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports. In addition, given the novelty of our therapeutics approach and technologies, detalimogene and any other product candidates that we may develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use of such products if approved. The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. FDA and other regulatory bodies may continually change the requirements for Chemistry, Manufacturing and Controls (CMC) and other aspects of product manufacturing such that the approval to continue a clinical trial and/or commercially sell a product may never occur. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted IND, BLA or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Detalimogene and any other product candidates that we may develop could be delayed in receiving or fail to receive regulatory approval for many reasons, including the following: â€¢the FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials; 45 â€¢we may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that detalimogene or any other product candidates that we may develop is safe and effective for its proposed indication or that a potential related companion diagnostic, should we develop one, is suitable to identify appropriate patient populations; â€¢the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA or other regulatory authorities for biologic product approval or continued clinical development; â€¢we may be unable to demonstrate that a product candidateâ€™s clinical and other benefits outweigh its safety risks; â€¢the FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; â€¢the data collected from clinical trials of detalimogene or any other product candidates that we may develop may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere; â€¢the FDA or other authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and â€¢the approval policies or regulations of the FDA or other regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of drugs and biologics in development, only a small percentage successfully complete the FDA or non-U.S. regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market detalimogene or any other product candidates that we may develop, which would significantly harm our business, financial condition, results of operations and prospects. We expect the novel nature of detalimogene or any other product candidates that we may develop to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be adversely affected. For example, the general approach for FDA approval of a new biologic or drug is for sponsors to seek licensure or approval based on dispositive data from well-controlled, Phase 3 clinical trials of the relevant product candidate in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We believe that we may be able to utilize the requirements defined in the FDAâ€™s guidance for industry on developing detalimogene or other product candidates for BCG-unresponsive high-risk NMIBC given the limited alternatives for treatments for cancer and other serious diseases, but the FDA may not agree with our plans or permit us to proceed under such alternative guidance. The FDA may also require an Advisory Committee to deliberate on the adequacy of the safety and efficacy data to support BLA approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of detalimogene or any other product candidates that we develop based on the completed clinical trials. Moreover, approval of genetic or biomarker diagnostic tests may be necessary in order to advance some of our product candidates to clinical trials or potential commercialization. In the future, regulatory agencies may require the development and approval of such tests. Accordingly, the regulatory approval pathway for such product candidates may be uncertain, complex, expensive and lengthy and approval may not be obtained. In addition, even if we were to obtain approval, regulatory authorities may approve detalimogene or any other product candidates that we may develop for fewer or more limited indications than we request, may not approve the price we intend to charge for our products (where such regulatory approvals are required), may grant approval contingent on the performance of costly post-marketing clinical trials or may approve that product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for detalimogene or any other product candidates that we may develop. If we experience delays in obtaining approval or if we fail to obtain approval of detalimogene or any other product candidates that we may develop, the commercial prospects for those product candidates may be harmed and our ability to generate revenues will be materially harmed. 46 We may not obtain or maintain regulatory approval in all jurisdictions in which such approval may be required or otherwise desirable or beneficial from a business perspective. Obtaining and maintaining regulatory approval of detalimogene or any other product candidates we develop in one jurisdiction does not mean that we will obtain and/or maintain regulatory approval of such product candidates in other jurisdictions, while a failure or delay in obtaining or maintaining regulatory approval of such product candidates in one jurisdiction may have a material adverse effect on the regulatory approval or maintenance process in other jurisdictions. Obtaining and maintaining regulatory approval of detalimogene or any other product candidates that we may develops in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in non-U.S. jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many non-U.S. jurisdictions, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions and such regulatory requirements can vary widely from country to country. Obtaining other regulatory approvals and compliance with other regulatory requirements could result in significant delays, difficulties and costs for us and could require additional preclinical studies or clinical trials, which could be costly and time-consuming and could delay or prevent the introduction of our products in certain countries. The non-U.S. regulatory approval process involves all of the risks associated with FDA approval, and may not offer certain potentially expedited development and approval pathways that exist in the United States. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with the regulatory requirements in international markets and/or obtain and maintain applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of detalimogene or any other product candidates that we may develop will be harmed.

Â Fast Track designation by the FDA for detalimogene may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that detalimogene or any future product candidate that may receive Fast Track designation will receive regulatory approval. The FDA has granted a Fast Track designation for detalimogene for the treatment of BCG-unresponsive, high-risk NMIBC patients with CIS, and we may seek Fast Track designations for other indications or future product candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, biologics are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate or development program is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Although we have received Fast Track designation for detalimogene for the treatment of BCG-unresponsive, high-risk NMIBC patients with CIS, and even if we receive additional Fast Track designations for other indications or any future product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that detalimogene or any future product candidate that may be granted Fast Track designation will receive marketing approval in the United States. Many product candidates that have received Fast Track designation have ultimately failed to obtain approval. We may seek priority review designation for detalimogene or any other product candidates we develop, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process. If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness of the treatment, the FDA may designate the marketing application for that product candidate for priority review. A priority review designation is intended to direct overall attention and resources to the evaluation 47 of such applications and to shorten the goal for the FDA to review an application to six months, rather than the standard review period of ten months. We may request priority review for one or more original BLAs for detalimogene or any other product candidates that we may develop s in the future. The FDA has broad discretion with respect to whether or not to grant priority review status to a marketing application, so even if we believe an application for a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle, or at all. Many product candidates that have received priority review designation have ultimately failed to obtain approval. Even if we receive regulatory approval of detalimogene or any other product candidates or therapies that we may develop, we will be subject to ongoing regulatory obligations, reporting requirements and continued regulatory review, which may result in significant additional expenses. If we fail to comply with regulatory requirements or experience unanticipated problems with our products or product candidates, we may be subject to substantial penalties, fines, delays, suspensions, refusals and withdrawals of approvals. If detalimogene or any other product candidates that we may develop are approved, they will be subject to ongoing regulatory requirements and reporting requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, recordkeeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable non-U.S. regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. Facilities of CMOs and testing laboratories are required to comply with extensive FDA, and non-U.S. regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, and in certain cases, current Good Tissue Practices (â€œcGTPâ€), regulations. As a result, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work with must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we receive for detalimogene or any other product candidates that we may develop may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require that we implement a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable non-U.S. regulatory authority approves detalimogene or any other product candidates that we may develop, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and establishment registration. The FDA may seek consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers, manufacturing processes or testing laboratories, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: â€¢restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; â€¢fines, warning or untitled letters or holds on clinical trials; â€¢refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; â€¢product seizure or detention or refusal to permit the import or export of our product candidates; and â€¢injunctions or the imposition of civil or criminal penalties. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations maybe enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the 48 adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Changes in regulatory requirements could result in delays or discontinuation of development of detalimogene or other product candidates or therapies that we may develop, or unexpected costs in obtaining or maintaining regulatory approval, and thereby adversely affect our business and results of operations. Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy and durability of effect must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. Because we are developing novel genetic medicine product candidates, the regulatory requirements that we will be subject to are continually evolving and may not be clear. Even with respect to more established products that fit into the category of genetic medicines, the regulatory landscape is still developing. For example, regulatory requirements governing genetic medicine products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing cell therapy products. Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union a special committee called the CAT was established within the EMA in accordance with Regulation (â€œECâ€) No 1394/2007 on advanced-therapy medicinal products (â€œATMPsâ€) to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include genetic medicine products. These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our genetic medicines and product candidates is new, we may face even more cumbersome and complex regulations than those emerging for cell therapy products. Furthermore, even if detalimogene or other product candidates that we may develop obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business. Our contract manufacturers are subject to significant regulation with respect to the manufacturing of our current and future product candidates. The manufacturing facilities on which we rely may not meet or continue to meet regulatory requirements and/or may have limited capacity. Contract manufacturers and their facilities are required to comply with extensive regulatory requirements, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. These regulations cover all aspects of manufacturing relating to our product candidates and components used in clinical studies and commercial production. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational product candidates and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We and our contract manufacturers must supply all necessary documentation in support of a BLA or Market Authorization Application (â€œMAAâ€) on a timely basis and must adhere to Good Laboratory Practices (â€œGLPâ€) and cGMP regulations enforced by the FDA and other regulatory authorities through their facilities inspection program. The facilities and quality systems of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the product candidates may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. Moreover, if our contract manufacturers fail to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or there are substantial manufacturing errors, this 49 could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns, revocation of regulatory approvals, or other problems that could seriously harm our business. Ongoing healthcare legislative and regulatory reform measures, including the U.S. federal governmentâ€™s determination that any of our product candidates, including detalimogene, is an â€œessentialâ€ biologic medicine, may have a material adverse effect on our business and results of operations. The United States and many non-U.S. jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription products. In recent years, Congress has considered reductions in Medicare reimbursement levels for products administered by physicians. The CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some products. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The ACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the ACA expanded manufacturersâ€™ rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic products, expanded the 340B program, and revised the definition of average manufacturer price, which could increase the amount of Medicaid rebates manufacturers are required to pay to states. The legislation also extended Medicaid rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those products. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the ACA. These regulations became effective on April 1, 2016. Since that time, there have been significant ongoing efforts to modify or eliminate the ACA. The Tax Cuts and Jobs Act, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the United States Internal Revenue Code of 1986, as amended (the â€œCodeâ€) or the individual mandate. Other legislative changes have been proposed and adopted since the passage of the ACA. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction (the â€œJoint Select Committeeâ€), to provide recommendations and legislative language that would significantly improve the short-term and long-term fiscal imbalance of the U.S. federal government. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislationâ€™s automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022. Under the Consolidated Appropriations Act, 2023, the 2% Medicare sequester is extended for the first six months of fiscal year 2032 and revises the sequester percentage up to 2% for fiscal years 2030 and 2031. These across-the-board spending cuts could adversely affect our future revenues, earnings, and cash flows. In August 2022, President Biden signed the Inflation Reduction Act of 2022 (the â€œIRAâ€). The IRA contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated â€œmaximum fair priceâ€ for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRAâ€™s Medicare drug price negotiation program. The effect of the IRA on our business and the pharmaceutical industry in general is not yet known. The ACA, has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the â€œindividual mandateâ€ was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire ACA. An appeal was taken to the U.S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions. 50 Further changes to and under the ACA remain possible but it is unknown what form any such changes or any law proposed to replace or revise the ACA would take, and how or whether it may affect our business in the future. We expect that changes to the ACA, the Medicare and Medicaid programs and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional federal, state and non-U.S. healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, including detalimogene, if approved, or additional pricing pressures. Any product candidates we develop, including detalimogene, may become subject to unfavorable or unprofitable third-party coverage and reimbursement practices, as well as pricing regulations. Patients rely on insurance coverage by third-party payors (third-party payors include Medicare and Medicaid (government payors) and commercial insurance companies such as Blue Cross Blue Shield, Humana, Cigna, etc.), to pay for products. The availability and extent of coverage and adequate reimbursement by third- party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. Private insurance companies, commercial payors and various other healthcare intermediaries such as pharmacy benefit managers may take steps to thwart physician and/or patient access to our products including not covering the product, blocking access to our products or adding step edits or prior approval requirements before reimbursing patients or health care providers for using our products. This could result in reduced or failure to achieve revenues and/or margins. In addition, third-party organizations that purport to study and issue reports regarding the pricing of certain therapeutic medicines may issue reports regarding our products that negatively affect pricing and our product use and uptake by physicians and patients. Additionally, private insurance companies are increasingly imposing utilization management tools, such as requiring prior authorization for a proprietary product if a generic product or less expensive product is available or requiring the patient to first fail on one or more generic or less expensive products before permitting access to a proprietary medicine. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. Factors payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. No uniform policy exists for coverage and reimbursement in the United States. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. As U.S. federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that our products, if approved, will be covered by private or public payors, and if covered, whether the reimbursement will be adequate or competitive with other marketed products. Such other actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and health care costs, which could negatively impact coverage and reimbursement for our products if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development. Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in the European Union, the United Kingdom, Japan and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates, including detalimogene, from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive 51 regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future or subject to recoupment or overpayment challenges. Drug marketing, price controls and reimbursement regulations may materially affect our ability to market and receive coverage for our product candidates, if approved, in the European Union, the United Kingdom, Japan and other non-U.S. jurisdictions. We intend to seek approval to market our product candidates, including detalimogene if approved, in both the United States and in selected non-U.S. jurisdictions. If we obtain approval in one or more non-U.S. jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some countries outside of the United States, particularly those in the European Union, the pricing of pharmaceutical products is subject to governmental control and other market regulations, which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If required to execute such a trial, we cannot be sure of a favorable outcome. In general, product prices under such systems are substantially lower than in the United States. Price controls in non-U.S. jurisdictions or changes in pricing regulations in such jurisdictions could reduce the amount we are able to charge for our product candidates. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures. Much like the federal AKS prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products are also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU member states, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physicianâ€™s employer, their competent professional organization and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. In addition, in most countries outside of the United States, including the European Economic Area (â€œEEAâ€), the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally, prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us and the potential profitability of any of our product candidates in those countries would be negatively affected. Guidelines and recommendations published by various organizations may impact the use or reimbursement of detalimogene, if approved, as well as other future products. Government authorities promulgate regulations and guidelines that may be directly applicable to us and any approved products. However, professional societies, practice management groups, insurance carriers, physiciansâ€™ groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payors, as well as patient communities. Recommendations by government authorities or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies, and a growing number of organizations are providing assessments of the value and pricing of pharmaceutical products. These assessments may come from private organizations, such as the Institute for Clinical and Economic Review (â€œICERâ€), which publish their findings and offer recommendations relating to the productsâ€™ reimbursement by government and private payors. On December 17, 2020, ICER published its final report assessing the effectiveness and value of nadofaragene firadenovec and oportuzumab monatox for BCG-unresponsive NMIBC, both of which are potential competitors to detalimogene. The guidance was updated on January 15, 2021. Nadofargene firadenovec, sold under the brand name Adstiladrin, is a FDA-approved genetic medicine approved in 2022 for the treatment of adult patients with high-risk BCG-unresponsive NMIBC with CIS with or without papillary 52 tumors; oportuzumab monatox, also known as Vicineum, is an experimental therapy that has been studied in a highly similar patient group. The findings of this or any future ICER report or similar recommendations or guidelines from ICER or similar third parties may affect our reputation as well as the perception of our value, and any recommendations or guidelines that result in decreased use or reimbursement of detalimogene, if approved or adopted into commercial or clinical practice, could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, the occurrence of any of the foregoing, or the perception by the investment community or shareholders that such recommendations or guidelines will result in decreased use or reimbursement of detalimogene, if approved, could adversely affect the market price of our securities. The effect, if any, of any ICER report, recommendations or guidelines on our any of our products relating to usage, dosage, administration, pricing, reimbursement or other matters is not foreseeable and we make no assurance regarding the effect of any current or future ICER report, recommendations or guidelines on our business. We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business and results of operations. We are subject to data privacy and protection laws, rules and regulations, as well as contractual obligations, that apply to the collection, transmission, storage, use and other processing of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, European Union and United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. There are numerous U.S. federal and state laws, rules and regulations governing the collection, sharing, use, retention, disclosure, security, transfer, storage and other processing of personal information, including federal and state data privacy and security laws, data breach notification laws, and data disposal laws. In particular, at the federal level, regulations promulgated pursuant to the HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future. At the federal level, we are also subject to, among other laws and regulations, the rules and regulations promulgated under the authority of the FTC (which has the authority to regulate and enforce against unfair or deceptive acts or practices in or affecting commerce, including acts and practices with respect to data privacy and security), as well as the Electronic Communication Privacy Act. The United States Congress also has considered, is currently considering, and may in the future consider, various proposals for comprehensive federal data privacy and security legislation, to which we may become subject if passed. If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached certain contracts or obligations. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. At the state level, we are subject to similar and sometimes more onerous data protection and privacy laws and regulations such as the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act (the â€œCPRAâ€) (collectively, the â€œCCPAâ€). The CCPA imposes many requirements on certain businesses that process the personal information of California residents, including requirements similar to those found in the General Data Protection Regulation (â€œGDPRâ€). For example, the CCPA requires covered businesses to provide notice to California residents regarding the information collected about them and how such information is used and shared, provides California residents the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of certain â€œsalesâ€ of their personal information. The CCPA provides for significant civil penalties and statutory damages for companies that violate its requirements, and also provides for a private right of action for certain data breaches that result in the loss of unencrypted personal information. This private right of action is expected to increase the likelihood of, and risks associated with, data breach litigation. The CPRA significantly expands the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. These provisions may apply to some of our business activities. In addition, other states, including Virginia and Colorado, already have passed comprehensive state-level data privacy and security laws, rules and regulations that share similarities with the CCPA. Other states are in the process of enacting or will be considering these laws in the future. Moreover, 53 laws in all 50 U.S. states require businesses to provide notice under certain circumstances to consumers whose personal information has been disclosed as a result of a data breach. These laws, and other similar laws that may be enacted in the future, may impact our business activities, including our identification of research subjects and ultimately the marketing and distribution of our products. Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA is regulated by the GDPR, which went into effect in May 2018 and imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations, including requiring data controllers and processors to maintain a record of their data processing and policies. Following the withdrawal of the United Kingdom from the European Union, the United Kingdomâ€™s Data Protection Act 2018 (the â€œU.K. GDPRâ€), which â€œimplementsâ€ and complements the GDPR and achieved formal approval by United Kingdomâ€™s monarchy on May 23, 2018, applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. While the GDPR and U.K. GDPR remain substantially similar for the time being, the U.K. government has announced that it would seek to chart its own path on data protection and reform its relevant laws, including in ways that may differ from the GDPR. While these developments increase uncertainty with regard to data protection regulation in the United Kingdom, even in their current, substantially similar form, the GDPR and U.K. GDPR can expose businesses to divergent parallel regimes that may be subject to potentially different interpretations and enforcement actions for certain violations and related uncertainty. If our or our service providersâ€™ privacy or data security measures fail to comply with the GDPR and U.K. GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros (or GBP17.5 million under the U.K. GDPR) or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. The GDPR places restrictions on the cross-border transfer of personal data from the EEA to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the EEA to other countries. Similar complexities and uncertainties also apply to transfers from the U.K. to third countries. In July 2020, the Court of Justice of the European Union (â€œCJEUâ€), invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEUâ€™s decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses (â€œSCCsâ€), for transfers of personal data from the EEA to the United States. While we were not self-certified under the EU-U.S. Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors. While we may take steps to mitigate the impact on us, such as implementing SCCs, the efficacy and longevity of these mechanisms remains uncertain. Moreover, in 2021, the European Commission adopted new SCCs, which impose on companies additional obligations relating to personal data transfers out of the EEA, including the obligation to update internal privacy practices, conduct transfer impact assessments and, as required, implement additional security measures. The new SCCs may increase the legal risks and liabilities under European Union laws associated with cross-border data transfers, and result in material increased compliance and operational costs. While the European Commission announced in March 2022 that an agreement in principle had been reached between European Union and U.S. authorities regarding a new transatlantic data privacy framework, no formal agreement has been finalized, and any such agreement, if formalized, is likely to face challenge at the CJEU. Moreover, while the U.K. GDPR is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under the GDPR. The United Kingdom has already determined that it considers all European Union and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the European Union and EEA remain unaffected. In addition, a decision from the European Commission appears to deem the United Kingdom as being â€œessentially adequateâ€ for purposes of data transfer from the EEA to the United Kingdom, such that SCCs are not required for the transfer of personal data from the EEA to the United Kingdom, although such decision will sunset in June 2025 unless extended and it may be revoked in the future by the European Commission if the United Kingdom data protection regime is reformed in ways that deviate substantially from the GDPR. Adding further complexity for international data flows, in March 2022, the United Kingdom adopted its own International Data Transfer Agreement for transfers of personal data out of the United Kingdom to so-called third countries, as well as an international data transfer addendum that can be used with the SCCs for the same purpose. The European Union has also proposed legislation that would regulate non-personal data and establish new cybersecurity standards, and other countries, including the United Kingdom, may similarly do so in the future. If we are otherwise unable to transfer data, including personal data, between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Beyond the GDPR and U.K. GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow the GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and any eventual sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions. While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and 54 applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Any failure, actual or perceived, to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, any failure, actual or perceived, to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business, financial condition, results of operations and prospects. Cyber-attacks or other failures in our or our third-party vendorsâ€™, contractorsâ€™ or consultantsâ€™ telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations. We, our programs, our CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology (â€œITâ€), systems and networks to process, transmit and store electronic information, including but not limited to intellectual property, proprietary business information and personal information, in connection with our business activities. Our internal IT systems and those of current and future third parties on which we rely may fail and are vulnerable to breakdown, breach, interruption or damage from cyber incidents, employee error or malfeasance, theft or misuse, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromises. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware (e.g., ransomware), viruses, spamming, phishing attacks, denial-of-service attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency, intensity, and sophistication. These threats pose a risk to the security of our, our programsâ€™, our CROsâ€™, third-party logistics providersâ€™, distributorsâ€™ and other contractorsâ€™ and consultantsâ€™ systems and networks, and the confidentiality, availability and integrity of our intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data, and health-related information. There can be no assurance that we or any of our third-party partners will be successful in preventing cyberattacks or successfully mitigating their effects. Advances in computer and software capabilities, encryption technology, and other discoveries increase the complexity of our technological environment, including how each interacts with our various software platforms. Such advances could delay or hinder our ability to conduct business or could compromise the integrity of our data, resulting in a material adverse impact on our financial condition and results of operations. The risk of system disruption is increased when significant system changes are undertaken. If we fail to timely integrate and update our information technology systems and processes, we may fail to realize the cost savings or operational benefits anticipated to be derived from these initiatives. We also may experience occasional system interruptions and delays that make our information technology systems unavailable or slow to respond, including the interaction of our information technology systems with those of third parties. A lack of sophistication or reliability of our information technology systems could adversely impact our operations and consumer service and could require major repairs, replacements or remodelings, resulting in significant costs. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, non-U.S. governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, varying parts of our workforce are currently working remotely on a part or full time basis. This could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile non-U.S. governments or agencies. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Similarly, there can be no assurance that our CROs, third-party logistics providers, distributors and other contractors, consultants and third parties will be successful in protecting our clinical and other data that is stored on their systems. Any loss of clinical trial data from our completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. We have experienced and expect to continue to experience actual and attempted cyberattacks of our IT networks, such as through phishing scams and ransomware. Although we do not believe that we have experienced any significant system failure, accident or security incidents to date, we cannot guarantee that we will not experience such incidents in the future. Any cyberattack that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding clinical trial participants or employees, data breach or destruction or loss of data could result in a violation of applicable U.S. and international privacy, data protection and other laws and regulations, require us to notify affected individuals or supervisory authorities, subject us to litigation and governmental investigations, proceedings and regulatory actions by federal, state and local 55 regulatory entities in the United States and by international regulatory entities, cause our exposure to material civil and/or criminal liability and cause us to breach our contractual obligations, which could result in significant legal and financial exposure and reputational damages. Further, we could be forced to expend significant financial and operational resources in response to a security breach, including repairing system damage, increasing security protection costs by deploying additional personnel and modifying or enhancing our protection technologies, investigating and remediating any information security vulnerabilities and defending against and resolving legal and regulatory claims, all of which could divert resources and the attention of our management and key personnel away from our business operations and adversely affect our business, financial condition and results of operations. As cyber threats continue to evolve, we may be required to incur significant additional expenses in order to implement further data protection measures or to remediate any information security vulnerability. Further, we do not maintain separate cyber liability insurance and our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim. Accordingly, if our cybersecurity measures, and those of our service providers, fail to protect against unauthorized access, attacks and the mishandling of data by our employees and third-party service providers, then our business, financial condition, results of operations and prospects could be adversely affected. Inadequate funding for, or changes in leadership at, or disruptions at the FDA, the SEC and other government agencies could hinder their ability to hire and retain key personnel, prevent new products and services from being developed, approved or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, passage of federal FDA user fee legislation every five years, ability to hire and retain key personnel and accept the payment of user fees, public health emergencies, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies or for the FDA to take action with respect to other regulatory matters, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown or other disruption could prevent the timely review of patent applications by the United States Patent and Trademark Office, or USPTO, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Our employees, independent contractors and contract manufacturers, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA and other regulatory bodies in non-U.S. jurisdictions, provide true, complete and accurate information to the FDA and other similar regulatory bodies in non-U.S. jurisdictions, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar non-U.S. laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly and our costs associated with compliance with these laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. 56 Our relationships with healthcare providers and physicians and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and result in diminished profits and future earnings and thereby adversely affect our business and results of operations. We are subject to applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the AKS and the FCA, which may constrain our business or financial arrangements and relationships through which we sell, market and distribute our products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry (e.g., healthcare providers, physicians and third-party payors), are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. We also may be subject to patient information and privacy and security regulation by both the federal government and the states and non-U.S. jurisdictions in which we conduct our business. The applicable federal, state and non-U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to: â€¢The AKS, which prohibits the knowing and willful offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including but not limited to cash, improper discounts, and free or reduced price items and services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, courts have found that if â€œone purposeâ€ of remuneration is to induce referrals, the AKS is violated. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. A claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of anti-kickback and other applicable laws can result in exclusion from federal health care programs and substantial civil and criminal penalties. â€¢The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. Some state law equivalents of the above federal laws, such as the AKS and FCA, apply to items or services regardless of whether the good or service was reimbursed by a government program, so called all-payor laws. These all-payor laws could apply to our sales and marketing activities even if the AKS and FCA laws are inapplicable. â€¢HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the AKS, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it. â€¢HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (â€œHITECHâ€), and their implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information also implicate our business. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneysâ€™ fees and costs associated with pursuing federal civil actions. In addition to other federal laws, state laws and non-U.S. laws, such as the General Data Protection Regulation in the European Union, create the potential for substantial penalties in the event of any non-compliance with the applicable data privacy and data protection laws. â€¢The federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Childrenâ€™s Health Insurance Program (with certain exceptions) to report annually to HHS, information related to 57 payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. For the data submitted on or after January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. States may also have similar reporting requirements related to payments made to clinical providers, and failure to comply with such requirements can adversely impact the business. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulatory guidance. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies, healthcare providers and other third parties, including charitable foundations, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert managementâ€™s attention from our business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA or an all-payor law, then we could be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert managementâ€™s attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. State and federal authorities have aggressively targeted pharmaceutical companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements with pharmacies and other healthcare providers that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines, have been ordered to implement extensive corrective action plans, and have in many cases become subject to consent decrees severely restricting the manner in which they conduct their business, among other consequences. Additionally, federal and state regulators have brought criminal actions against individual employees responsible for alleged violations. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. Also, the U.S. Foreign Corrupt Practices Act (â€œFCPAâ€) and similar worldwide anti-bribery laws, including the Canadian Corruption of Foreign Public Officials Act, generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, partners or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation. For additional information regarding the compliance of our operations with the FCPA and non-U.S. laws and regulations, see the Risk Factor entitled â€œAdditional laws and regulations governing international operations may preclude or delay us from developing, manufacturing or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs.â€ We are subject to certain U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations thereof. Among other matters, U.S. and non-U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, the â€œTrade Lawsâ€) prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of the Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time, including when and if we conduct clinical trials outside the United States. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, even if we do not explicitly authorize or have prior knowledge of such activities. 58 Risks Related to International Operations We are an international organization and we plan to expand operations internationally where we have limited operating experience and where we may be subject to increased regulatory risks and local competition. If we are unsuccessful in any efforts to expand internationally, our business and results of operations may be adversely affected. We are already an international organization and we plan to further expand our operations internationally. We currently source drug product excipients and other product components that are critical to our manufacturing processes from CMOs located in the European Union. In the future, we expect to opportunistically engage with CMOs located in other non-U.S. jurisdictions to facilitate the manufacture of our products on a basis that is cost effective and responsive to customer demand. As part of our business strategy, we plan to commercialize detalimogene and other products we may develop for sale in the United States and non-U.S. jurisdictions. Our business strategy incorporates potential international operational expansion, independently and through third parties as we seek to obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the United States. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including, but not limited to: â€¢multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; â€¢failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; â€¢rejection or qualification of non-U.S. clinical trial data by the competent authorities of other countries; â€¢delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad; â€¢additional potentially relevant third-party patent and other intellectual property rights; â€¢complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property; â€¢difficulties in staffing and managing non-U.S. operations; â€¢complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems; â€¢limits in our ability to penetrate international markets; â€¢financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to non-U.S. currency exchange rate fluctuations; â€¢trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments; â€¢workforce uncertainty in countries where labor unrest is more common than in the United States; â€¢natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including a COVID-19 resurgence, and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions; certain expenses including, among other things, expenses for travel, translation and insurance; and â€¢regulatory and compliance risks that relate to anti-corruption compliance and recordkeeping that may fall within the purview of the FCPA, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries. Any of these factors could harm our future international expansion and operations and, consequently, our results of operations. Global economic uncertainty, changes in geopolitical conditions and weakening product demand caused by political instability, changes in trade agreements and disputes, such as the armed conflicts between Russia and Ukraine and in the Middle East and other macroeconomic factors, could adversely affect our business and results of operations. Our operations and performance depend on global, regional and U.S. economic and geopolitical conditions. General worldwide economic conditions have experienced significant instability in recent years, including due to recent global economic uncertainty and turbulent financial market conditions. The armed conflict in the Middle East has created volatility in the global capital markets and is expected to have further global economic consequences. Russiaâ€™s ongoing military invasion of Ukraine has triggered significant sanctions from U.S. and European leaders and disruptions to financial markets around the world. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a â€œtrade war.â€ In addition, changes in political conditions in China and changes in the state of China-U.S. relations, including any tensions relating to potential military conflict between China and Taiwan, are difficult to predict and could adversely affect our business. Furthermore, if other 59 countries, including the United States, become further involved in the conflict, we could face significant adverse effects to our business and financial condition. The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact our business in the future. For example, increasing inflation has raised operating costs for us and many businesses, and, in the future, could impact demand, pricing or the cost we incur to manufacture our product candidates, foreign exchange rates (including in particular U.S. dollar and Canadian dollar exchange rates) or employee wages. Among other potential effects, continued increased inflation or interest rates may result in reduced liquidity and limits on our ability to access credit or otherwise raise capital. The Federal Reserve has previously raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks and creating new, unforeseen risks to our operations. Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. These conditions make it extremely difficult for us to accurately forecast and plan future business activities. The above factors, including a number of other known and unknown economic and geopolitical factors in the United States and abroad, could ultimately have material adverse effects on our business, financial condition, results of operations and prospects. We expect certain of our research and development and manufacturing activities may take place in non-U.S. jurisdictions, such as China, through third-party CROs, collaborators or manufacturers. A significant disruption in the operation of those CROs, collaborators or manufacturers could materially adversely affect our business and results of operations. We may contract many of our research, manufacturing and preclinical activities to third parties outside the United States, including without limitation, in China. Any disruption in the operations of such third parties or in their ability to meet our needs, whether as a result of a natural disaster, war or other causes, could impair our ability to operate our business on a day-to-day basis and to continue development of our programs. Furthermore, since many of these third parties are located outside the United States, we are exposed to the possibility of disruption and increased costs in the event of changes in the policies of the United States or non-U.S. governments, war, political unrest or unstable economic conditions in any of the countries where we conduct such activities. For example, a war or trade war could lead to tariffs, embargoes, sanctions or other limitations on trade, including without limitation those placed on Russia as a result of its ongoing military invasion of Ukraine, that may affect our ability to source from affected third parties the reagents and raw materials used in our product candidates. Additionally, a natural disaster, war, civil or political unrest or similar circumstances could hinder our ability to maintain or initiate clinical studies at our preferred sites, causing trial initiation or implementation delays. Any of these matters could materially and adversely affect our product development timelines, business, financial condition, results of operations and prospects. Additional laws and regulations governing international operations may preclude or delay us from developing, manufacturing or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs. As an international company with operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any non-U.S. official, political party or candidate for the purpose of influencing any act or decision of the non-U.S. entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government and doctors and other hospital employees are considered non-U.S. officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we continue to expand our presence outside of the United States, we will need to dedicate additional resources to complying with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. 60 The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. securities exchanges for violations of the FCPAâ€™s accounting provisions. Risks Related to Our Intellectual Property If we are unable to obtain and maintain, enforce and defend patent protection for any product candidates we develop or for our novel genetic medicine platform, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products or technology similar or identical to ours and our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected. Our success depends in large part on our and our licensorsâ€™ ability to seek, obtain and maintain patent and other intellectual property protection in the United States, Canada and other jurisdictions with respect to any product candidates we may develop and our technology, including our genetic medicine platform, manufacturing processes and their respective components, formulations, combination therapies, methods of treatment, processes and development that are important to our business, as well as successfully defending these patents and other intellectual property against third-party challenges. The risks associated with patent rights generally apply to patent rights that we in-license now or in the future, as well as patent rights that we may own now or in the future. We have sought, and will seek, to protect our proprietary position by filing patent applications in the United States and abroad related to certain technologies and our genetic medicine platform that are important to our business. However, elements of our patent portfolio are at an early stage and there can be no assurance as to whether or when such patent applications will issue as granted patents. Our ability to stop third parties from making, using, selling, marketing, offering to sell, importing and commercializing any product candidates we may develop and our technology is dependent upon the extent to which we and our licensors have rights under valid and enforceable patents and other intellectual property that cover our genetic medicine platform and proprietary technology. If we are or our licensors are unable to secure, maintain, defend and enforce patents and other intellectual property with respect to any product candidates or technology that we may develop, it would have a material adverse effect on our business, financial condition, results of operations and prospects. We own certain granted patents and pending patent applications which cover our genetic medicine platform, use and/or function, product candidates and their use, and manufacturing processes, as applicable. Our pending Patent Cooperation Treaty (â€œPCTâ€) patent application, and any PCT application we may file in the future, is not eligible to become issued patents until, among other things, we file one or more national stage patent applications within 30 to 32 months, depending on the jurisdiction, from such applicationâ€™s priority date in the jurisdictions in which we are seeking patent protection. Similarly, should we in the future file a pending provisional patent application such application would not be eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of such provisional patent applicationâ€™s filing date. If we do not timely file such national stage patent applications or non-provisional patent applications, we may lose our priority date with respect to such PCT or provisional patent applications, respectively, and any patent protection on the inventions disclosed in such PCT or provisional patent applications, respectively. While we and our licensors intend to timely file national stage and non-provisional patent applications relating to our PCT and provisional patent applications, respectively, we cannot predict whether any such patent applications will result in the issuance of patents. If we or our licensors do not successfully obtain issued patents, or, if the scope of any patent protection we or our licensors obtain is not sufficiently broad, we will be unable to prevent others from using any product candidates we may develop or our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies. Any failure to obtain or maintain patent protection with respect to genetic medicine platform, manufacturing processes or our product candidates and technology would have a material adverse effect on our business, financial condition, results of operations and prospects. The patent prosecution process is expensive, time-consuming and complex, and we and our licensors may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We and our licensors may not be able to obtain, maintain or defend patents and patent applications due to the subject matter claimed in such patents and patent applications being in the public domain. For example, in some cases, the work of certain academic researchers in the genetic medicine field has entered or will enter the public domain, which may compromise our and our licensorsâ€™ ability to obtain patent protection for certain inventions related to or building upon such prior work. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we would not be able to prevent any third-party from using any of our technology that is in the public domain to compete with our product candidates and technology. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of patent rights are highly uncertain. Our pending and future owned and licensed patent applications may not result in patents being issued which protect our technology or product candidates, effectively prevent others from commercializing competitive technologies and products or otherwise provide any competitive advantage. In fact, patent applications may not issue as 61 patents at all, and even if such patent applications do issue as patents, they may not issue in a form, or with a scope of claims, that will provide us with any meaningful protection, prevent others from competing with us or otherwise provide us with any competitive advantage. In addition, the scope of claims in a patent application can be significantly reduced before the patent is issued, and such scope of an issued patent can be reinterpreted after issuance, and changes in either the patent laws or interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patent rights or narrow the scope of our patent protection. Furthermore, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Third parties have developed technologies that may be related or competitive to our own technologies and product candidates and may have filed or may file patent applications, or may have obtained or may obtain issued patents, claiming inventions that may overlap or conflict with those claimed in our owned or licensed patent applications or issued patents. We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates and technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know for certain whether the inventors of our owned or licensed patents and patent applications were the first to make the inventions claimed in any owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third-party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable. We may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, inventorship disputes may arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and other jurisdictions. For example, we may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office (â€œUSPTOâ€) challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patentâ€™s issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We may become involved in opposition, derivation, re-examination, inter partes review, post-grant review or interference proceedings and similar proceedings in non-U.S. jurisdictions (for example, opposition proceedings) challenging the validity, priority or other features of patentability of our owned or licensed patent rights. In addition, a third-party may claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any litigation or patent office proceeding could put one or more of our owned or licensed patents at risk of being invalidated, ruled unenforceable or interpreted narrowly and could allow third parties to commercialize products identical or similar to any product candidates we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a non-U.S. patent office, that challenge priority of invention or other features of patentability. Such challenges and proceedings may result in loss of patent rights, exclusivity, freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the scope and duration of the patent protection of our technology and any product candidates we may develop. Such challenges and proceedings may also result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other interim proceedings or developments related to such challenges and proceedings and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares. We may in the future co-own intellectual property rights relating to our genetic medicine platform and our future product candidates with third parties. In addition, our licensors may co-own the patent rights we in-license with other third parties with whom we do not have a direct relationship. If we or our licensors do not have exclusive control of the grant of licenses under any such third-party co-ownersâ€™ interest in such patent rights or we or our licensors are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patent rights in order to enforce such patent rights against third parties and such cooperation may not be provided to us. Further, any such co-owner may be able to license a co-owned patent to a third-party we believe infringes such patent, preventing us from obtaining compensation or other remedies from such third-party through litigation or settlement arrangements. We may also become engaged in disputes with our co-owners related to patent prosecution strategy or the apportionment of costs associated with the prosecution, maintenance or enforcement of co-owned patents or patent applications. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. 62 Issued patents covering our product candidates or genetic medicine platform could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other jurisdictions. If we initiated legal proceedings against a third-party to enforce a patent covering our genetic medicine platform, product candidates or other technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in non-U.S. jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our product candidates or other technologies or prevent third parties from competing with us. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third-party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the genetic medicine platform, our product candidates or other technologies. Such a loss of patent protection would have a material adverse effect on our business, financial condition, results of operations and prospects. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications will be due to be paid to the USPTO and various non-U.S. government patent agencies over the lifetime of our owned or licensed patents and patent applications. In certain circumstances, we may rely on our licensing partners to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and non-U.S. patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We may also be dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technologies, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Changes in either patent laws or interpretation of the patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates and genetic medicine platform. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Prior to March 2013, in the United States, the first to invent an invention was entitled to a patent claiming the invention, while outside the United States, the first to file a patent application was entitled to the patent, assuming that other requirements for patentability were met. After March 2013, under the Leahy-Smith America Invents Act (the â€œAmerica Invents Actâ€) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent on an invention, regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after the date of invention but before the filing date of our owned or in-licensed patent application could therefore be awarded a patent covering an invention of ours, even if we had made the invention before it was made by the third-party. This will require us and our licensors to be aware going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technologies and the prior art allow our technologies to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (1) file any patent application related to our technologies or product candidates or (2) invent any of the inventions claimed in our patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submissions of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because the evidentiary standard in USPTO proceedings is lower than the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid, even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use USPTO proceedings to invalidate our owned or in-licensed patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Accordingly, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the enforcement or defense of our owned and in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. 63 In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our owned or in-licensed patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Patent terms may be inadequate to protect our competitive position, product candidates or genetic medicine platform for an adequate amount of time, and we may need to obtain patent term extension and equivalent extensions outside of the United States for our product candidates or genetic medicine platform. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest filing date of the first U.S. non-provisional patent application to which the patent claims priority. Various adjustments and extensions may be available, but the life of a patent and the protection it affords is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Depending upon the timing, duration and specifics of any FDA marketing approval of our product candidates or genetic medicine platform, one or more U.S. patents that we own or license may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (â€œthe Hatch-Waxman Amendmentsâ€). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug or biologic. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In Europe, supplementary protection certificates are available to extend a patent term up to five years to compensate for patent term lost during regulatory review, and can be extended for an additional six months if data from clinical trials is obtained in accordance with an agreed-upon pediatric investigation plan. Although all countries in Europe must provide supplementary protection certificates, there is no unified legislation among European countries and so supplementary protection certificates must be applied for and granted on a country-by-country basis. This can lead to a substantial cost to apply for and receive these certificates, which may vary among countries or not be provided at all. We may not be granted any extensions for which we apply in the United States or any other jurisdiction because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third-party, we would need the cooperation of that third-party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may be able to enter the market sooner, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Further, recent judicial decisions in the U.S. raised questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in the future and whether patent expiration dates may be impacted. Our rights to develop and commercialize our product candidates and genetic medicine platform may be subject, in part, to the terms and conditions of licenses. We are reliant upon licenses to certain intellectual property and proprietary technologies from third parties that are important or necessary to the development of our technologies and product candidates. We have entered into license agreements with third parties and may need to obtain additional licenses from others to advance our research or allow commercialization of product candidates we may develop. It is possible that we may be unable to obtain or maintain additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technologies, product candidates, or the methods for manufacturing them or to develop or license replacement technologies, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, or may be significantly delayed in doing so, which could significantly harm our competitive position, business, financial condition, results of operations and prospects. We cannot provide any assurances that third-party patents do not exist which might be enforced against our technologies and product candidates resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. 64 Our current and future licenses may not provide exclusive rights to use such intellectual property and proprietary technologies in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technologies and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technologies that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business or in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensorsâ€™ infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected. Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technologies. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate our license agreements, thereby removing our ability to develop and commercialize products and technologies covered by these license agreements. If these license agreements are terminated for this reason or any other reason, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business and results of operations. We may be unable to acquire or in-license intellectual property rights from third parties relating to, or necessary for, the development of our product candidates on commercially reasonable terms, or at all. In that event, we may be unable to develop or commercialize such product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. We may be required by the FDA or comparable non-U.S. regulatory authorities to provide a companion diagnostic test or tests with our product candidates, which test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. The licensing and acquisition of third-party intellectual property rights is a competitive area and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth may be harmed. 65 If we fail to comply with our obligations under the agreements pursuant to which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose the rights to intellectual property that are important to our business. We have a non-exclusive license under certain patents and/or know-how to develop and commercialize certain elements or components of our potential product candidates which may not be available elsewhere. Our existing license agreements impose, and we expect that any future license agreements will impose on us, various obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. If any of our licenses are terminated and we are not able to negotiate other agreements for use of the intellectual property protections underlying these product candidates, we would not be able to manufacture and market these potential products, which would have a material adverse effect on our business, financial condition, results of operations and prospects. â€¢Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including: â€¢the scope of rights granted under the license agreement and other interpretation-related issues; â€¢our financial or other obligations under the license agreement; â€¢the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; â€¢the sublicensing of patent and other rights; â€¢our diligence obligations under the license agreement and what activities satisfy those diligence obligations; â€¢the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any licensors or partnersâ€™ licensors; and â€¢the priority of invention of patented technology. In addition, certain provisions in our license agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. In addition, certain of these license agreements, may not be assignable by us without the consent of the respective licensor, which may have an adverse effect on our ability to engage in certain transactions. Moreover, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors. We may not be able to protect our intellectual property and proprietary rights throughout the world. Filing, prosecuting and defending patents on our product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside of the United States and Canada are less extensive than those in the United States and Canada. In addition, the laws of countries outside the United States and Canada may not protect our or our licensorsâ€™ rights to the same extent as the laws of the United States and Canada, even in jurisdictions where we or our licensors do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our licensorsâ€™ inventions in all countries outside the United States and Canada, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our inventions in and into the United States, Canada or other jurisdictions. Competitors may use our technologies in jurisdictions where we and our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States and Canada. These products may compete with our products and our or our licensorsâ€™ patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in non-U.S. jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our or our licensorsâ€™ intellectual property and proprietary rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our or our licensorsâ€™ patents at risk of being invalidated or interpreted narrowly, could put our or our licensorsâ€™ patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. 66 Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be harmed and our business, financial condition, results of operations and prospects may be adversely affected. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries and we will not have the benefit of patent protection in such countries, which could have an adverse effect on our operations or commercial prospects within those countries or ability to pursue action against potential competitors. Further, in Europe, a new unitary patent system came into effect on June 1, 2023. Under the unitary patent system, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (UPC). European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes. Â We may be involved in legal proceedings in relation to intellectual property rights and to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming, and we may not have the financial resources to do so. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may choose to challenge the patentability of claims in a third-partyâ€™s U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-examination, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-partyâ€™s patent in patent opposition proceedings in the European Patent Office (â€œEPOâ€), or another non-U.S. patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications are typically not published in the United States until 18 months after their respective filing dates. Further, publications in the scientific literature often lag behind actual discoveries. Consequently, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. It is possible that our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours and that those patent applications may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert managementâ€™s time and expend other resources, even if we are successful. Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome in an interference proceeding could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common shares. 67 Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors or other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and prospects. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be adversely affected. In addition to the protection afforded by patents, we rely on trade secret protection, confidentiality agreements, and license and other agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some countries outside of the United States do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition. Some courts both within and outside the United States and Canada are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our genetic medicine platform and product candidates, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms and related processes are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that certain information and data concerning our business made known to the individual or entity during the course of the partyâ€™s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. However, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. However, we cannot provide assurance that these agreements and policies will not be breached by our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors and that our trade secrets and other proprietary and confidential information will not be disclosed to publicly or to competitors. If any of the employees, consultants, outside scientific collaborators, sponsored researchers and other advisors who are parties to these agreements breach or violate the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or other third parties. Competitors or third parties could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside the scope of our intellectual property rights. We will have limited recourse if this occurs. Furthermore, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitorsâ€™ products, our business, financial condition, results of operations and prospects could be materially and adversely affected. 68 Third-party claims of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our novel genetic medicine platform, our product candidates and other technologies. The field of biotherapeutics, including the development of genetic medicines, is competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed and other third-party intellectual property and proprietary rights in the future. Our commercial success depends in part on our and our licensorsâ€™ ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in jurisdictions outside of the United States. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including inter partes review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future. Numerous U.S., Canadian and other foreign issued patents and pending patent applications owned by third parties exist relating to genetic medicine technologies and products and in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our genetic medicine platform, product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot be sure that our genetic medicine platform, product candidates and other technologies that we have developed, are developing or may develop in the future do not infringe existing patents or will not infringe future patents owned by third parties. Many companies and institutions have filed, and continue to file, patent applications related to genetic medicine and related manufacturing methods. Some of these patent applications have already been allowed or issued and others may issue in the future. It is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our genetic medicine platform, product candidates and other technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may not be aware of patents that have already been issued and that a third-party, for example, a competitor in the fields in which we are developing our genetic medicine platform, product candidates and other technologies might assert are infringed by our current or future product candidates, genetic medicine platform or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our genetic medicine platform, product candidates and other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our genetic medicine platform, product candidates and other technologies, could be found to be infringed by our genetic medicine platform, product candidates and other technologies. In addition, because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be currently pending patent applications that may later result in issued patents that our genetic medicine platform, product candidates and other technologies may infringe. Furthermore, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States may remain confidential until a patent issues. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or technologies. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our genetic medicine platform, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. Third parties have patents and may obtain patents in the future and may claim that the manufacture, use or sale of our genetic medicine platform, product candidates or other technologies infringes upon these patents. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our genetic medicine platform, product candidates or other technologies. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent or find that our product candidates or technology did not infringe any such claims. Further, even if we were successful in defending against any such claims, such claims could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. If we are found to infringe, misappropriate or otherwise violate a third-partyâ€™s valid and enforceable patent rights, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay substantial license fees or royalties or both and the rights granted to us might be non-exclusive, which could result in our competitors and other 69 third parties gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our genetic medicine platform, product candidates or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing, manufacturing or commercializing our infringing genetic medicine platform, product candidates or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneysâ€™ fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize the genetic medicine platform, our product candidates or other technologies, which could harm our business significantly. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our owned or licensed patent portfolio may therefore have no deterrent effect. Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could have an adverse effect on our ability to raise additional funds and attract collaborators and could impair our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Many of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individualâ€™s current or former employer. In many cases we rely on our employeesâ€™ and contractorsâ€™ representations and warranties that they will not engage in practices that could subject us to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such intellectual property rights would harm our business and may prevent us from successfully commercializing any product candidates we may develop or at all. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize any product candidates we may develop and our technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our scientific and management personnel. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third-party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. Disputes about the ownership of intellectual property that we own may have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patent rights. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technology and any product candidates we may develop. Such challenges may also result in our inability to develop, manufacture or commercialize our technology and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patent 70 rights are threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technology and product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: â€¢others may be able to make next generation immunotherapies for cancer or other diseases that are similar to ours but that are not covered by the claims of the patents that we own or have licensed; â€¢we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have licensed; â€¢we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions; â€¢others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; â€¢it is possible that our pending patent applications or those that we license will not lead to issued patents; â€¢issued patents that we own or have licensed may be held invalid or unenforceable, including as a result of legal challenges by our competitors; â€¢others may have access to the same intellectual property rights licensed to us in the future on a nonexclusive basis; â€¢our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; â€¢we may choose not to file a patent for certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property; â€¢we may not develop additional proprietary technologies that are patentable; and â€¢the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects. We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position. Our current and future trademark applications in the United States and in foreign jurisdictions may not be allowed or may subsequently be opposed. Once filed and registered, our registered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects. Risks Related to Acquisitions and Collaborations We will need to grow the size of our organization, both organically and through acquisitions, and we may experience difficulties identifying and hiring the right employees and successfully managing this growth. As of October 31, 2024, we had 57 employees. As our development and commercialization plans and strategies develop, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of technology research, product development and manufacturing, regulatory affairs and, if any product candidates are submitted for or receive 71 marketing approval, sales, marketing and distribution. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including: â€¢managing our preclinical studies and clinical trials effectively; â€¢identifying, recruiting, integrating, maintaining and motivating additional employees; â€¢managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors, licensors and other third parties; â€¢improving our operational, financial and management controls, reporting systems and procedures; and â€¢expanding our facilities. Our future financial performance and our ability to commercialize our product candidates may depend, in part, on our ability to effectively manage any future growth and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, contractors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management and manufacturing. There can be no assurance that the services of independent organizations, advisors, contractors and consultants will continue to be available to us on a timely basis when needed or that we will be able to find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by independent organizations, advisors, contractors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing independent organizations, advisors, contractors or consultants or find other competent resources on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding the roster of independent organizations, advisors and consultants on whom we rely on an outsourced basis, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Acquisitions, collaborations or other strategic partnerships may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks. We may from time to time evaluate collaborations and strategic partnerships or potential acquisitions, including licensing or acquiring molecules, biologics, or gene therapies, etc., for use in our genetic medicine platform, intellectual property rights, technologies or businesses. For example, we may seek collaboration arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. Collaboration, strategic partnerships or acquisitions entail numerous risks, including: â€¢increased operating expenses and cash requirements; â€¢reduced control over the development of certain of aspects of detalimogene, our genetic medicine platform or other product candidates; â€¢the assumption of indebtedness or contingent liabilities; â€¢the issuance of our equity securities; â€¢assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel; â€¢the diversion of our managementâ€™s attention from our internal product development efforts and initiatives in pursuing such a strategic merger or acquisition; â€¢retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships; â€¢risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status and their existing products or product candidates and marketing approvals; â€¢failure to recognize the synergies or other benefits intended for the acquisition, partnership or collaboration; and â€¢potential inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products 72 that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations and prospects. We may make acquisitions to expand our business and as a result, our results of operations may be adversely affected. We may choose to expand our current business through the acquisition of other businesses, products or technologies, or through strategic alliances. Acquisitions involve numerous risks, including the following: â€¢the possibility that we will pay more than the value derived from the acquisition which could result in future non-cash impairment charges, and incremental operating losses; â€¢difficulties in integration of the operations, technologies and products of the acquired companies, which may require significant attention of our management that otherwise would be available for the ongoing development of our business; â€¢the assumption of certain known and unknown liabilities of the acquired companies; â€¢difficulties in retaining key relationships with employees, customers, collaborators, vendors and suppliers of the acquired company; â€¢and in the case of acquisitions outside of the jurisdictions we currently operate in, the need to address the particular economic, currency, political, and regulatory risks associated with specific countries, particularly those related to our collection of sensitive data, regulatory approvals, and tax management, which may result in significant additional costs or management overhead for our business. Any of these factors could have a negative impact on our business, financial condition, results of operations and prospects. Risks Related to Investment in our Securities Because we are a Canadian company, shareholder protections differ from shareholder protections in the United States and elsewhere, and we are subject to a variety of additional risks that may negatively impact our operations. We are organized and exist under the laws of British Columbia, Canada and, accordingly, are governed by the BCBCA and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction. We are subject to special considerations or risks associated with companies operating in Canada that may, at any time differ from the considerations and risks of companies operating in the United States, including any of the following: â€¢political regimes, rules and regulations or currency conversion or corporate withholding taxes on individuals; â€¢tariffs and trade barriers; â€¢regulations related to customs and import/export matters; â€¢longer payment cycles; â€¢tax issues, such as tax law changes and variations in tax laws as compared to the United States; â€¢requirements to maintain a company nexus with Canada or a particular province of Canada; â€¢currency fluctuations and exchange controls; â€¢challenges in collecting accounts receivable; â€¢cultural and language differences; â€¢employment regulations; â€¢crime, strikes, riots, civil disturbances, terrorist attacks and wars; and â€¢deterioration of political relations with the United States, which could result in uncertainty and/or changes in or to existing trade treaties. In particular, we are subject to the risk of changes in economic conditions, social conditions and political conditions inherent in Canada, including changes in laws and policies that govern international investment, as well as changes in U.S. laws and regulations relating to international trade and investment, including the new trilateral trade agreement among the United States, Mexico and Canada called the United States-Mexico- Canada Agreement (the â€œUSMCAâ€), which has been ratified by all three countries. The USMCA entered into force on July 1, 2020 and superseded the North American Free Trade Agreement. Although we believe that there have been no immediate effects on our operations with respect to the USMCA, we cannot predict future developments in the political climate involving the United States, Mexico and Canada and such developments may have a material adverse effect on our business, financial condition and results of operations. 73 The Articles and certain Canadian legislation contain provisions that may have the effect of delaying, preventing or making undesirable an acquisition of all or a significant portion of our shares or assets or preventing a change in control. Certain provisions of our Articles and certain provisions under the BCBCA, together or separately, could discourage, delay or prevent a merger, acquisition or other change in control of us that shareholders may consider favorable, including transactions in which they might otherwise receive a premium for their common shares. These provisions include the establishment of a staggered board of directors, which divides the board into three groups, with directors in each group serving a three-year term. The existence of a staggered board can make it more difficult for shareholders to replace or remove incumbent members of our Board of Directors. As such, these provisions could also limit the price that investors might be willing to pay in the future for our common shares, thereby depressing the market price of our common shares. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our Board of Directors. Among other things, these provisions include the following: â€¢shareholders cannot amend our Articles unless such amendment is approved by shareholders holding at least 66 2/3% of the shares entitled to vote on such approval; â€¢our Board of Directors may, without shareholder approval, issue preferred shares in one or more series having any terms, conditions, rights, preferences and privileges as the board of directors may determine; and â€¢shareholders must give advance notice to nominate directors or to submit proposals for consideration at shareholdersâ€™ meetings. A non-Canadian must file an application for review with the Minister responsible for the Investment Canada Act and obtain approval of the Minister prior to acquiring control of a â€œCanadian businessâ€ within the meaning of the Investment Canada Act, where prescribed financial thresholds are exceeded. A reviewable acquisition may not proceed unless the Minister is satisfied that the investment is likely to be of net benefit to Canada. If the applicable financial thresholds were exceeded such that a net benefit to Canada review would be required, this could prevent or delay a change of control and may eliminate or limit strategic opportunities for shareholders to sell their common shares. Furthermore, limitations on the ability to acquire and hold our common shares may be imposed under the Competition Act (Canada). This legislation has a pre-merger notification regime and mandatory waiting period that applies to certain types of transactions that meet specified financial thresholds, and permits the Commissioner of Competition to review any acquisition, directly or indirectly, including through the acquisition of shares, of control over or of a significant interest in us. The Articles designate specific courts in Canada and the United States as the exclusive forum for certain litigation that may be initiated by our shareholders without our prior written consent, which could limit our shareholdersâ€™ ability to obtain a favorable judicial forum for disputes with us. Pursuant to the Articles, unless we consent in writing to the selection of an alternative forum, the courts of the Province of British Columbia and the appellate courts therefrom shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on our behalf; (b) any action or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us; (c) any action or proceeding asserting a claim arising out of any provision of the BCBCA or the Articles (as either may be amended from time to time); or (d) any action or proceeding asserting a claim or otherwise related to our affairs (the â€œCanadian Forum Provisionâ€). In addition, the Articles further provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Delaware shall be the sole and exclusive forum for resolving any complaint filed in the United States asserting a cause of action arising under the Securities Act of 1933, as amended (the â€œSecurities Actâ€) or the Exchange Act (the â€œU.S. Forum Provisionâ€). In addition, the Articles provide that any person or entity purchasing or otherwise acquiring any interest in our common shares is deemed to have notice of and consented to the Canadian Forum Provision and the U.S. Forum Provision; provided, however, that shareholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder. The Canadian Forum Provision and the U.S. Forum Provision in the Articles may impose additional litigation costs on shareholders in pursuing any such claims. Additionally, the forum selection clauses in the Articles may limit our shareholdersâ€™ ability to bring a claim in a judicial forum that they find favorable for disputes with our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our shareholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are â€œfacially validâ€ under Delaware law, there is uncertainty as to whether other courts, including courts in Canada and other courts within the United States, will enforce our U.S. Forum Provision. If the U.S. Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The U.S. Forum Provision may also impose additional litigation costs on shareholders who assert that the provision is not enforceable or invalid. The courts of the Province of British Columbia and the United States District Court for the District of Delaware may also reach different judgments or results than would other courts, including courts where a shareholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders. 74 Because we are a Canadian company, it may be difficult to serve legal process or enforce judgments against us. We are incorporated and maintain operations in Canada. In addition, certain of our directors reside in the United States, while others reside outside of the United States. Accordingly, service of process upon us may be difficult to obtain within the United States. Furthermore, because substantially all of our assets are located outside the United States, any judgment obtained in the United States against us, including one predicated on the civil liability provisions of the U.S. federal securities laws, may not be collectible within the United States. Therefore, it may not be possible to enforce those actions against us. In addition, it may be difficult to assert U.S. securities law claims in original actions instituted in Canada. Canadian courts may refuse to hear a claim based on an alleged violation of U.S. securities laws against us or these persons on the grounds that Canada is not the most appropriate forum in which to bring such a claim. Even if a Canadian court agrees to hear a claim, it may determine that Canadian law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Canadian law. Furthermore, it may not be possible to subject foreign persons or entities to the jurisdiction of the courts in Canada. Similarly, to the extent that our assets are located in Canada, investors may have difficulty collecting from us any judgments obtained in the U.S. courts and predicated on the civil liability provisions of U.S. securities provisions. Our ability to use net operating loss carry-forwards and certain other tax attributes are limited. In general terms, where control of a corporation is acquired or deemed to be acquired, which for our Company as a result of the Reverse Recapitalization, the corporation is subject to a â€œloss restriction eventâ€, and the corporationâ€™s non-capital loss carryforwards, other losses and certain other tax attributes are subject to limitation and possibly expiry after the loss restriction event. Similar rules apply for Canadian provincial purposes. Consequently, we may not be able to utilize a material portion of our non-capital loss carryforwards and certain other tax attributes in certain circumstances. For U.S. tax purposes, net operating loss carryforwards allow companies to use past year net operating losses to offset against future yearsâ€™ profits, if any, to reduce future tax liabilities. Sections 382 and 383 of the Code limit a corporationâ€™s ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporationâ€™s business, results of operations, financial condition and cash flow. Even if another ownership change has not occurred and does not occur as a result of this offering, additional ownership changes may occur in the future as a result of additional equity offerings or events over we will have little or no control, including purchases and sales of its equity by its five percent security holders, the emergence of new five percent security holders, redemptions of its securities or certain changes in the ownership of any of its five percent security holders. We believe that we are and there is a significant risk that we may continue to be a passive foreign investment company (a â€œPFICâ€), which could result in adverse U.S. federal income tax consequences to U.S. Holders of our Common Shares or Warrants. In general and as relevant here, a non-U.S. corporation is a PFIC for U.S. federal income tax purposes for any taxable year in which (i) 50% or more of the value of its assets (generally determined on the basis of a quarterly average) consists of assets, including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, that produce, or are held for the production of, passive income, or (ii) 75% or more of its gross income, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, consists of passive income. Passive income generally includes dividends, interest, rents and royalties (other than rents or royalties derived from the active conduct of a trade or business) and gains from the disposition of passive assets. Cash and cash equivalents are generally passive assets. The value of goodwill will generally be treated as an active or passive asset based on the nature of the income produced in the activity to which the goodwill is attributable. Prior to the commercialization of our drug candidates, our income may be primarily passive. Accordingly, we believe we may have met the definition of PFIC for U.S. federal income tax purposes for the tax year ended October 31, 2023 and the tax year ended October 31, 2024 and there is a significant risk that we will be a PFIC for our current or any future taxable year. If we are a PFIC for any taxable year during which a U.S. Holder (as defined below) owns Common Shares, the U.S. Holder generally will be subject to adverse U.S. federal income tax consequences, including increased tax liability on disposition gains and certain â€œexcess distributionsâ€ and additional reporting requirements, unless the U.S. Holder makes (a) a qualified electing fund (â€œQEFâ€) election or a mark-to-market election for the first taxable year for which we are or were a PFIC and in which such U.S. Holder held (or was deemed to hold) such Common Shares and maintain such election or (b) a QEF election along with an applicable purging election (collectively, the â€œPFIC Electionsâ€). Under proposed Treasury regulations relating to PFICs which have a retroactive effective date, the PFIC rules may apply to rights to acquire shares of a PFIC as if they were shares, and thus could apply to dispositions (other than exercises) of Warrants. PFIC Elections may not be made with respect to Warrants. U.S. Holders of Common Shares or Warrants should consult their tax advisors regarding the application of the PFIC rules to us and the risks of owning equity securities, including warrants, in a company that may be a PFIC. 75 Â As a result of making and maintaining a timely and valid QEF election (if eligible to do so), a U.S. Holder of Common Shares must include in income such U.S. Holderâ€™s pro rata share of our net capital gains (as long-term capital gain) and other earnings and profits (as ordinary income), on a current basis, whether or not distributed. A U.S. Holder generally may make a separate election to defer the payment of taxes on undistributed income inclusions under the QEF rules, but if deferred, any such taxes will be subject to an interest charge. A subsequent distribution of such earnings and profits that were previously included in income should generally not be taxable as a dividend to such U.S. Holder. The tax basis of a U.S. Holderâ€™s shares in a PFIC with respect to which a QEF election has been made will be increased by amounts that are included in income, and decreased by amounts distributed but not taxed as dividends, under the above rules. Â The QEF election is made on a shareholder-by-shareholder basis and, once made, can be revoked only with the consent of the IRS. A U.S. Holder generally makes a QEF election by attaching a completed IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund), including the information provided in a PFIC Annual Information Statement from us, to a timely filed U.S. federal income tax return for the tax year to which the election relates. In the event that we determine that we are a PFIC for U.S. federal income tax purposes for any taxable year, we will, upon request of a holder of Common Shares, provide a PFIC Annual Information Statement to such holder. Retroactive QEF elections generally may be made only by filing a protective statement with such federal income tax return and if certain other conditions are met or with the consent of the IRS. U.S. Holders are urged to consult their tax advisors regarding the availability and tax consequences of a retroactive QEF election under their particular circumstances. Â As an alternative to a QEF election, if a U.S. Holder owns shares in a company that is a PFIC and the shares are â€œregularly tradedâ€ on a â€œqualified exchange,â€ such U.S. Holder could make a mark-to-market election that would result in tax treatment different from that under the interest charge rules described above. The Common Shares will be treated as regularly traded for any calendar year in which more than a de minimis quantity of the Common Shares are traded on a qualified exchange on at least 15 days during each calendar quarter. Nasdaq, where the Common Shares are listed, is a qualified exchange for this purpose. Â Such electing U.S. Holder generally will include for each of its taxable years as ordinary income the excess, if any, of the fair market value of its Common Shares at the end of such year over its adjusted basis in its Common Shares. The U.S. Holder also will recognize an ordinary loss in respect of the excess, if any, of its adjusted basis of its Common Shares over the fair market value of its Common Shares at the end of its taxable year (but only to the extent of the net amount of previously included in income as a result of the mark-to-market election). The U.S. Holderâ€™s basis in its Common Shares will be adjusted to reflect any such income or loss amounts. Any gain recognized on a sale or other taxable disposition of its Common Shares will be treated as ordinary income, and any loss will be treated as an ordinary loss (but only to the extent of the net amount previously included in income as a result of the mark-to-market election, with any excess treated as a capital loss). Â For purposes of this Risk Factor, a â€œU.S. Holderâ€ is a beneficial holder of securities who or that, for U.S. federal income tax purposes is (i) an individual who is a United States citizen or resident of the United States; (ii) a corporation or other entity treated as a corporation for United States federal income tax purposes created in, or organized under the law of, the United States or any state or political subdivision thereof; (iii) an estate the income of which is includible in gross income for United States federal income tax purposes regardless of its source; or (iv) a trust (A) the administration of which is subject to the primary supervision of a United States court and which has one or more United States persons (within the meaning of the Code) who have the authority to control all substantial decisions of the trust or (B) that has in effect a valid election under applicable Treasury regulations to be treated as a United States person. Our Articles include provisions that may discourage takeover attempts, including a classified or â€œstaggeredâ€ board. Certain provisions in our articles (together with the articles of incorporation and notice of articles, the â€œArticlesâ€) may have the effect of deterring coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the bidder and by encouraging prospective acquirers to negotiate with our Board of Directors rather than to attempt a hostile takeover. These provisions include, among others: â€¢the existence of a classified or â€œstaggeredâ€ board; â€¢the right of our Board of Directors to issue preferred stock and to determine the voting, dividend, and other rights of preferred stock without shareholder approval; â€¢the ability of our directors, and not shareholders, to fill vacancies on our Board in most circumstances and to determine the size of our Board of Directors; â€¢the requirement for two-thirds of the votes cast by shareholders on a special resolution in order to remove directors or amend certain provisions of the Articles; and â€¢the absence of cumulative rights in the election of directors. 76 While these provisions are not intended to make us immune from takeovers, they will apply even if the offer may be considered beneficial by some shareholders and may delay or prevent an acquisition that our Board of Directors determines is not in the best interests of us and our shareholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors. Certain of our financing agreements place operating restrictions on its business, which may limit its flexibility to respond to opportunities and may have a material adverse effect on its business, financial condition and results of operations. On May 16, 2023, we entered into a letter agreement with Investissement Quebec (â€œIQâ€) and FEAC (the â€œIQ Letter Agreementâ€), in connection with IQâ€™s investment in the 2023 Convertible Notes. Among the terms of the IQ Letter Agreement, we agreed to comply with certain covenants that may restrict its ability to expand its operations or engage and pursue certain business opportunities. From the time that IQ first holds our Common Shares until the earlier of (1) the date IQ ceases to hold at least 2% of our outstanding shares on a fully-diluted basis, and (2) the date that is five years after the date of the IQ Letter Agreement, unless we receive prior written consent from IQ: (i) we must maintain our head office in the Province of QuÃ©bec, and (ii) we shall cause ours company to (A) maintain operations in the Province of QuÃ©bec, (B) maintain a research and development center in the Province of QuÃ©bec, and (C) engage at least 20 employees who are residents and work in the Province of QuÃ©bec (the â€œEmployment Thresholdâ€), provided that, if in good faith, our Board of Directors determines that maintaining the Employment Threshold puts us at risk of bankruptcy, insolvency or determines that it is in the best interests of our Company to effect a general reduction in workforce, IQ shall not unreasonably withhold consent to reduce the Employment Threshold. Additionally, IQ will, for so long as IQ holds shares representing, in the aggregate, ownership of greater than 2% of our shares on a fully diluted basis, be permitted to have an observer attend any meeting of our Board of Directors subject to the terms and conditions of a board observer agreement to be negotiated in good faith between us and IQ. Our compliance with these provisions may affect its ability to react to changes in industry conditions, take advantage of business opportunities it believes to be desirable, hire and retain critical personnel, execute or product development and commercialization initiatives, among other potential effects. Risks Related to Our Common Shares and Warrants and to Being a Public Company Sales of Common Shares, or the perception of such sales, by us or the Selling Holders in the public market or otherwise could cause the market price for our Common Shares to decline and certain Selling Holders still may receive a significant rate of return. On November 13, 2024, we filed (i) a registration statement on Form S-3 (File No. 333-283202) (the â€œresale registration statementâ€) with the SEC to register the issuance of up to an aggregate of 8,511,968 Common Shares upon the exercise of a like number of Warrants as well as the resale from time to time by the selling securityholders named in the resale registration statement (the â€œSelling Holdersâ€) of (a) up to 46,977,183 of our Common Shares (which includes 6,289,198 Common Shares that may be issued upon exercise of the Warrants); and (b) up to 6,289,198 of our Warrants and (ii) a universal shelf registration statement on Form S-3 (File No. 333-283201) (the â€œshelf registration statementâ€) with the SEC to register the issuance by us of up to $300 million of securities. The resale registration statement and the shelf registration statement each became effective November 21, 2024. The sale of Common Shares in the public market or otherwise, including sales pursuant to the resale registration statement or the shelf registration statement, or the perception that such sales could occur, could harm the prevailing market price of our Common Shares. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of Common Shares may cause the market price of our securities to drop significantly, even if our business is doing well. We have agreed, at our expense, to prepare and file the resale registration statement with the SEC. The Common Shares and Warrants being offered for resale in the prospectus which forms a part of the resale registration statement, represent approximately 92.2% of our total outstanding Common Shares and approximately 73.9% of our outstanding Warrants, respectively, as of the date of such prospectus. The resale, or expected or potential resale, of a substantial number of our Common Shares in the public market could adversely affect the market price for our Common Shares and make it more difficult for you to sell your Common Shares at times and prices that you feel are appropriate. Furthermore, we expect that, because there will be a large number of shares registered pursuant to the resale registration statement, Selling Holders will continue to offer the securities covered by the resale registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to a resale registration statement may continue for an extended period of time. Certain existing securityholders acquired their securities in our Company at prices that may be below the current trading price of such securities, and may experience a positive rate of return based on such current trading price. Future investors in our Company may not experience a similar rate of return. Certain securityholders in the Company, including certain of the Selling Holders, acquired Common Shares or Warrants at prices that may be below the current trading price of such securities and may experience a positive rate of return based on such current 77 trading price. On December 16, 2024, the closing price of our Common Shares was $6.30 per share and the closing price for our Warrants was $0.90 per warrant. Selling Holders in some instances may earn a significant positive rate of return on their investment depending on the market price of our Common Shares and Warrants at the time that such Selling Holders choose to sell their securities. The Selling Holders acquired the securities offered for resale in exchange for non cash consideration or at effective purchase prices that may range from significantly below to above current trading prices. Investors who purchase our Common Shares and Warrants on the Nasdaq may not experience a similar rate of return on the securities they purchased due to differences in the purchase prices and the current trading price. There is no assurance that Warrants will be and/or remain â€œin the moneyâ€ prior to their expiration or that the holders of Warrants will elect to exercise any or all of their Warrants for cash; the Warrants may expire worthless. The exercise price for our Warrants is $11.50 per Common Share. The Warrants will expire on October 31, 2028, the date that is five years after the completion of the Reverse Recapitalization (as defined herein). The Warrantsâ€™ cashless exercise period ended when the Companyâ€™s registration statement on Form S-1 (File No. 333-275700) was declared effective on March 5, 2024. We will receive proceeds from Warrants only in the event that such Warrants are exercised for cash. We believe the likelihood that holders will exercise their Warrants will depend on the trading price of our Common Shares. If the market price for our Common Shares is less than the exercise price of Warrants, we believe the holders of Warrants will be unlikely to exercise them. If the market price for our Common Shares exceeds the exercise price of the Warrants, it is more likely that holders of the Warrants will exercise them. There is no assurance that Warrants will be â€œin the moneyâ€ prior to their expiration or that the holders of Warrants will elect to exercise any or all of their Warrants for cash. As such, the Warrants may expire worthless. We will continue to incur increased costs as a result of operating as a public company, and the requirements for public companies may strain resources and divert managementâ€™s attention. The individuals who constitute our management team have not previously managed our business, or in some cases any business, as a publicly traded company. Compliance with public company requirements places significant additional demands on management and will require them to enhance investor relations, legal, financial reporting and corporate communications functions. Our management is required to devote substantial time to maintaining and improving its internal controls over financial reporting and the requirements of being a public company. These additional efforts may strain resources and divert managementâ€™s attention from other business concerns and affect its ability to accurately report its financial results and prevent fraud, which could adversely affect our business and profitability. We may be unable to satisfy Nasdaqâ€™s continued listing requirements in the future, which could limit investorsâ€™ ability to effect transactions in our securities and subject it to additional trading restrictions. Our Common Shares and Warrants commenced trading on Nasdaq under the tickers â€œENGNâ€ and â€œENGNWâ€, respectively, on November 1, 2023. We are required to meet Nasdaqâ€™s continued listing requirements and may be unable to meet those requirements. Although our securities are listed on the Nasdaq as of the date of this Annual Report, we may be unable to maintain the listing of our securities in the future. If we fail to meet the continued listing requirements and the Nasdaq delists our securities from its exchange, there could be significant material adverse consequences, including: â€¢a limited availability of market quotations for our securities; â€¢reduced liquidity for our securities; â€¢a determination that our Common Shares are a â€œpenny stockâ€ which will require brokers trading in our Common Shares to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; â€¢a limited amount of news and analyst coverage for us; and â€¢a decreased ability to obtain capital or pursue acquisitions by issuing additional equity or convertible securities. We will continue to incur increased costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. As a publicly traded company, we will continue to incur significant legal, accounting and other expenses. In addition, new and changing laws, regulations and standards relating to corporate governance and public disclosure for public companies, including the Dodd-Frank Act, the Sarbanes-Oxley Act, regulations related thereto and the rules and regulations of the SEC and Nasdaq, have 78 increased the costs and the time that must be devoted to compliance matters. We expect these rules and regulations will increase our legal and financial costs and lead to a diversion of management time and attention from revenue-generating activities. A market for our securities may not develop or be sustained, which would adversely affect the liquidity and price of our securities. The price of our securities may fluctuate significantly due to the marketâ€™s reaction to general market and economic conditions. An active trading market for our securities may never develop or, if it develops, it may not be sustained, which could have a material adverse effect on the liquidity and price of our securities. Â The trading price of our Common Shares could be highly volatile, and purchasers of our Common Shares could incur substantial losses. The price of our Common Shares is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their Common Shares at or above the price at which they paid. The market price for our Common Shares may be influenced by those factors discussed in this â€œRisk Factorsâ€ section and many others, including: â€¢results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector; â€¢our ability to enroll patients in our future clinical trials; â€¢our ability to obtain and maintain regulatory approval of detalimogene or any other product candidates we develop or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process; â€¢regulatory or legal developments in the United States and foreign countries; â€¢changes in the structure of healthcare payment systems; â€¢the success or failure of our efforts to develop, acquire, or license detalimogene or any future product candidates; â€¢innovations, clinical trial results, product approvals and other developments regarding our competitors; â€¢announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments; â€¢manufacturing, supply, or distribution delays or shortages; â€¢any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners; â€¢achievement of expected product sales and profitability; â€¢variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors; â€¢market conditions in the biopharmaceutical sector and issuance of securities analystsâ€™ reports or recommendations; â€¢trading volume of our Common Shares; â€¢an inability to obtain additional funding; â€¢sales of our Common Shares by us, our insiders or our shareholders; â€¢general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control; â€¢additions or departures of senior management, directors or key personnel; â€¢intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property; â€¢changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and â€¢changes in accounting standards, policies, guidelines, interpretations or principles. We could be a target of securities class action and derivative lawsuits, which could result in substantial costs. Our share price may be volatile and, in the past, companies that have experienced volatility in the market price of their shares have from time to time been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of managementâ€™s attention and resources, which could have a 79 material adverse effect on our business, financial condition, results of operations and prospects. Any adverse determination in litigation could also subject us to significant liabilities. If securities or industry analysts do not publish research about us at all or publish inaccurate or unfavorable research about us or our business, the market price and/or the trading volume of our Common Shares could decline. The trading market for our Common Shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover us, then the market price for our Common Shares and Warrants could be adversely affected. If one or more of the analysts who cover us downgrade a recommendation with regard to our Common Shares, publish inaccurate or unfavorable research about us or our business, cease to cover us or fail to publish reports on it regularly, the market price and/or the trading volume of our Common Shares and Warrants could decline. 80 Item 1B. Unresolved Staff Comments. Not applicable. Item 1C. Cybersecurity. Cybersecurity Risk Management and Strategy We have implemented cybersecurity risk management procedures, in accordance with our risk profile and business size, that are designed to identify, assess, and mitigate risks from current and emerging cybersecurity threats. Our cybersecurity procedures, which are informed by the National Institute of Standards and Technology cybersecurity framework, are supported by a third-party managed services provider that assists us in managing our IT systems. We maintain cyber insurance coverage; however, such insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks, and other related breaches.Our cybersecurity procedures are comprised of a variety of tools designed to protect our data and information technology systems, including but not limited to endpoint protection and network security measures, that are supported by our third-party service providers. We also have a process to require our employees to undergo cybersecurity awareness training. Further, we plan to implement a process to review risks to our Company in connection with certain third-party providers and vendors, which we expect will involve assessments through vendor questionnaires, as appropriate.To date, we have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party IT service providers and vendors have from time to time experienced threats that could affect our information or systems. For more information, see, â€œRisk Factors,â€ in this Annual Report.Cybersecurity GovernanceOur cybersecurity program is managed and directed by our Vice President, Information Technology, or IT, who has approximately 20 years of experience in information technology and information systems management. Our Vice President, IT reports to our Chief Financial Officer. One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight. Our Audit Committee is responsible for overseeing the Companyâ€™s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes cybersecurity risk. A cybersecurity update is provided at least annually, or more frequently as needed, to the Audit Committee by members of management responsible for managing cybersecurity risks. Item 2. Properties. As of October 31, 2024, we have leased approximately 10,620 sq. feet of laboratory and office space at 4868 Rue Levy Montreal, QC H4R 2P1 and 6,450 sq. feet of office space at 200 Fifth Avenue, Waltham, Massachusetts 02451. We believe our current facilities are sufficient for our current needs. To meet future needs of our business, we may lease additional or alternate space. We believe that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations. Item 3. Legal Proceedings. From time to time, we may be involved in legal proceedings that arise in the regular course of our business. Our management believes that we are not currently involved in any legal proceedings that are likely to have a significant negative effect on our business. However, legal proceedings can negatively affect our business, financial condition, results, and future prospects, regardless of the outcome, due to costs associated with defense and settlement, as well as the diversion of management resources, among other factors. Item 4. Mine Safety Disclosures. Not applicable. 82 PART II Item 5. Market for Registrantâ€™s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities. Our Common Shares and Warrants commenced trading on the Nasdaq Global Market under the symbols â€œENGNâ€ and â€œENGNW,â€ respectively on November 1, 2023. Shareholders As of December 16, 2024, there were approximately 50,976,676 Common Shares issued and outstanding held of record by 64 holders, and approximately 8,511,968 Warrants held of record by 17 holders, each exercisable for one Common Share at a price of $11.50 per share. Additionally, we agreed to issue to the Lenders (as defined herein) Warrants to acquire up to 138,696 Common Shares, of which 62,413 have been issued. The actual number of holders of our Common Shares is greater than this number of record holders, and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities. Dividends We have not paid any cash dividends on our Common Shares to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of the Board of Directors at such time. Securities Authorized for Issuance Under Equity Compensation Plans Â Equity Compensation Plan Information as of October 31, 2024 Â Plan category Â Number of securities to be issued upon exercise of outstanding options, warrants, and rights Â Â Weighted-average exercise price of outstanding options, warrants, and rights Â Â Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) Â Â Â (a) Â Â (b) Â Â (c) Â Equity compensation plans approved by security holders (1)(2) Â Â 4,391,512 Â Â $ 6.17 Â Â Â 2,752,889 Â Equity compensation plans not approved by security holders (3) Â Â 1,643,000 Â Â $ 8.69 Â Â Â â€” Â Total Â Â 6,034,512 Â Â $ 6.88 Â Â Â 2,752,889 Â Â (1) On October 31, 2023, upon completion of the Business Combination, the enGene Holdings Inc. 2023 Incentive Equity Plan became effective, which authorized enGene to issue 2,607,943 Common Shares under the plan, plus 2,706,941 Common Shares that are subject to outstanding grants under the enGene Inc. employee share option and equity incentive plans. On May 15, 2024, the Companyâ€™s shareholders approved the adoption of the Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan, which authorizes enGene to issue 4,554,169 Common Shares under the plan, plus 2,706,941 Common Shares that are subject to outstanding grants under the enGene Inc. employee share option and equity incentive plans. Â (2) As part of the Business Combination, the 2,706,941 Common Shares subject to outstanding grants under the enGene Inc. employee share option and equity incentive plans were modified to have the exercises price converted from the Canadian Dollar to the United States Dollar, at the exchange rate in effect on the date immediately prior to the close of the Business Combination. Â (3) Consists of Common Shares issuable upon exercise of outstanding stock options granted pursuant to the Nasdaq inducement grant exception as a component of employment compensation for employees. The inducement grants were approved by our compensation committee and were made as an inducement material to employees entering into employment with us in accordance with Nasdaq Listing Rule 5635(c)(4). Recent Sales of Unregistered Securities February 2024 PIPE Financing On February 13, 2024, the Company entered into subscription agreements in connection with the February 2024 PIPE Financing (as defined herein) pursuant to which we issued and sold in a private placement 20,000,000 Common Shares at a price of $10.00 per share. The aggregate gross proceeds from the February 2024 PIPE Financing were $200 million, before deducting offering expenses of $12.4 million. The February 2024 PIPE Financing closed on February 20, 2024. 83 October 2024 PIPE Financing On October 24, 2024, the Company entered into subscription agreements in connection with the October 2024 PIPE Financing (as defined herein) pursuant to which we issued and sold in a private placement 6,758,311 Common Shares at a price of $8.90 per share. The aggregate gross proceeds from the October 2024 PIPE Financing were $60.1 million, before deducting offering expenses of $3.8 million. The October 2024 PIPE Financing closed on October 29, 2024. Cashless Warrant Exercises Through October 31, 2024, 1,379,391 of the Companyâ€™s public Warrants were exercised by investors on a cashless basis, with such cashless Warrant exercises resulting in the issuance of 383,355 Common Shares. The sales of the securities described above were exempt from the registration requirements of the Securities Act in reliance on the exemptions afforded by Section 4(a)(2) of the Securities Act with respect to the February 2024 PIPE Financing and October 2024 PIPE Financing, and Section 3(a)(9) of the Securities Act with respect to the Cashless Warrant Exercises. No sales involved underwriters, underwriting discounts or commissions or public offerings of securities of the Registrant. Issuer Purchases of Equity Securities We did not purchase any of our Common Shares or other equity securities during the quarter or fiscal year ended October 31, 2024. Item 6. [Reserved] 84 Item 7. Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations. Throughout this section, unless otherwise noted, â€œweâ€, â€œourâ€, â€œusâ€, â€œenGeneâ€ and the â€œCompanyâ€ refer to enGene Holdings Inc. and all of its subsidiaries following the consummation of the Reverse Recapitalization (as defined below). enGene Holdings Inc. is the publicly traded parent company resulting from the Reverse Recapitalization, in which shareholders of enGene Inc. and Forbion European Acquisition Company exchanged their shares for shares in enGene Holdings Inc. The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements as of October 31, 2024 and 2023 and for the fiscal years ended October 31, 2024 and 2023, and the related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See the sections titled â€œSpecial Note Regarding Forward-Looking Statementsâ€ and â€œRisk Factorsâ€ in this Annual Report for a discussion of forward-looking statements and important factors that could cause actual results to differ materially from the results described in or implied by these forward-looking statements. We operate as a single operating segment focused on research, discovery, and clinical development of human genetic medicine products. Our fiscal year is the year ended October 31. Overview Business Overview We are a clinical-stage biotechnology company focused on developing genetic medicines to improve the lives of patients suffering from bladder cancer. We are developing non-viral genetic medicines based on our novel and proprietary dually derived chitosan, or â€œDDXâ€, gene delivery platform, which allows localized delivery of complex genetic cargos directly to mucosal tissues and other organs. Our lead product candidate, detalimogene voraplasmid, or detalimogene, formerly known as EG-70, is a therapy designed to generate a local immune reaction in proximity to tumors. We believe this enables the immune system to durably clear the tumor and develop memory to resist recurrence. Because this treatment is designed to work by delivering genetic cargo to the broader tumor tissue environment rather than tumor cells specifically, we believe it has the potential to be widely utilized across tumor types. Currently, we are developing detalimogene as a monotherapy to treat non-muscle invasive bladder cancer (â€œNMIBCâ€) with carcinoma in situ (â€œCISâ€) in patients that have been unresponsive to treatment with Bacillus Calmette-GuÃ©rin, or â€œBCG,â€ or what is referred to as â€œBCG-unresponsive NMIBC with CIS.â€ We are also exploring the clinical application of detalimogene to other forms of NMIBC, namely, papillary-only BCG-unresponsive NMIBC (i.e., NMIBC without CIS), as well as BCG-naÃ¯ve NMIBC patients with CIS and BCG-exposed NMIBC patients with CIS (i.e., patients who have been treated with some BCG but who do not qualify as BCG-unresponsive in accordance with FDA and urology practice guidelines). Our detalimogene program is currently enrolling patients in a combined Phase 1/2 open-label study with a pivotal cohort, referred to as â€œLEGENDâ€. The Phase 2 portion of LEGEND is enrolling three cohorts: cohort 1 is a pivotal cohort enrolling BCG-unresponsive NMIBC patients with CIS; cohort 2 is enrolling patients with BCG-naÃ¯ve NMIBC patients with CIS (cohort 2a) and BCG-exposed NMIBC patients with CIS (cohort 2b); and cohort 3 is enrolling patients with BCG-unresponsive NMIBC who have papillary disease only (i.e., no CIS). In addition, our preclinical research is focused on expanding the cancer indications that can be treated with detalimogene as well as discovering new opportunities to apply our DDX technology platform to treat other indications with high unmet medical needs. Since our inception, we have devoted substantially all of our efforts to organizing and staffing our Company, business planning, raising capital, establishing our intellectual property portfolio, acquiring or discovering product candidates, research and development activities for our primary program, detalimogene voraplasmid, or detalimogene. We do not have any products approved for sale and have not generated any revenue from product sales. We operate as a single operating segment focused on research, discovery, and clinical development of detalimogene. Since our merger with Forbion European Acquisition Company (â€œFEACâ€) (the â€œReverse Recapitalizationâ€), we have financed the Company through a series of Private Investment in Public Entity (â€œPIPEâ€) financings and debt facility with Hercules. We have never been profitable and have incurred net losses since inception. Our net losses were $55.1 million and $99.9 million for the years ended October 31, 2024 and 2023, respectively. As of October 31, 2024 and 2023, we had an accumulated deficit of $254.7 million and $199.6 million, respectively, and cash and cash equivalents of $173.0 million and $81.5 million, respectively. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we advance the ongoing LEGEND study of detalimogene, including the pivotal cohort of patients with BCG-unresponsive NMIBC, to completion; execute on our plan to file a Biologics License Application with the FDA in mid-2026; and pursue potential pipeline expansion via additional detalimogene development opportunities and other compounds. In addition, we expect to incur significant expenses as we establish medical affairs, sales, marketing and distribution infrastructure and capabilities to support the potential commercial launch of detalimogene and significant additional commercialization-related expenses, if and when detalimogene is approved. As a result, we expect to need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate 85 significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings, or other capital sources, which could include potential collaboration agreements, strategic alliances, or licensing arrangements. We may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.â€ As of October 31, 2024, we had $173.0 million in cash and cash equivalents and $124.9 million in marketable securities, mainly US Treasury Bonds. We believe that our existing cash and cash equivalents and marketable securities as of October 31, 2024 will be sufficient to fund our operating expenses, debt obligations, and capital expenditure requirements for at least the next 12 months from the issuance date of the consolidated financial statements included within this Annual Report. While we have historically been successful in securing financing, raising additional funds is dependent on a number of factors outside of our control, and as such there is no assurance that we will be able to do so in the future. See â€œLiquidity and Capital Resourcesâ€ below. Reverse Recapitalization On October 31, 2023, the Company, FEAC, and enGene Inc., a corporation incorporated under the laws of Canada (now known as â€œenGene Incâ€ or â€œOld enGeneâ€), consummated the merger (the â€œReverse Recapitalizationâ€) pursuant to a business combination agreement, dated as of May 16, 2023 (the â€œMerger Agreementâ€). The transaction was accounted for as a â€œreverse recapitalizationâ€ in accordance with U.S. GAAP. Under this method of accounting, FEAC was treated as the â€œacquiredâ€ company for financial reporting purposes. This determination is and was primarily based on the fact that subsequent to the Reverse Recapitalization, senior management of Old enGene continues as senior management of the combined company; Old enGene identifies a majority of the members of the board of directors of the combined company; the name of the combined company is enGene Holdings Inc. and it utilizes Old enGeneâ€™s current headquarters, and Old enGeneâ€™s operations comprise the ongoing operations of the combined company. Accordingly, for accounting purposes, the Company is considered to be a continuation of Old enGene, with the net identifiable assets of FEAC deemed to have been acquired by Old enGene in exchange for Old enGene common shares accompanied by a recapitalization, with no goodwill or intangible assets recorded. The number of number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization, have been retrospectively restated to reflect an exchange ratio of approximately 0.18048 (the â€œExchange Ratioâ€) established in the Merger Agreement. Operations prior to the Reverse Recapitalization are those of Old enGene. As a result of the Reverse Recapitalization, the Company became a publicly traded company, and listed its Common Shares and Warrants on the Nasdaq Global Market under the symbols â€œENGNâ€ and â€œENGNW,â€ respectively, commencing trading on November 1, 2023, with Old enGene, a subsidiary of the Company continuing the existing business operations. Immediately after giving effect to the Reverse Recapitalization and the PIPE financing conducted by the Company as part of the Reverse Recapitalization (the â€œPIPE Financingâ€), the Company had 23,197,976 Common Shares and 10,411,641 Warrants outstanding. As part of the Reverse Recapitalization, the Company received net proceeds of $7.4 million from the FEAC trust account, net of the redemption payment to FEACâ€™s public shareholders and FEAC expenses. As a part of the Reverse Recapitalization, the Company raised an aggregate amount of $56.9 million through a series of convertible debt investments made to Old enGene which were exchanged for equity interests in the Company pursuant to the Reverse Recapitalization. Components of Our Results of Operations Revenue We do not have any product candidates approved for sale, have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products or from other sources in the near future, if at all. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate, if ever. If our development efforts for our current lead product candidate, detalimogene, or additional product candidates that we may develop in the future are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales and payments from such collaboration or license agreements. 86 Operating Expenses Research and Development Research and development expenses account for a significant portion of our operating expenses and consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include: Direct Costs: â€¢expenses incurred under agreements with CROs that are primarily engaged in the oversight and conduct of our clinical trials; CDMOs that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services; â€¢the cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches; â€¢costs of outside consultants, including their fees, share-based compensation and related travel expenses; â€¢costs related to compliance with quality and regulatory requirements; â€¢payments made under third-party licensing agreements; offset by â€¢refundable tax credits, which were moved to the direct expense category in 2023 to conform with current year presentation. Indirect Costs: â€¢personnel-related expenses including, salaries, benefits, share-based compensation and other related costs for individuals involved in research and development activities; and â€¢facilities and other expenses not directly tied to a program. We expense research and development costs as incurred. We recognize direct development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors or our estimate of the level of service that has been performed at each reporting date. Payments for these development activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid expenses or accrued expenses. A significant portion of our research and development costs to date have been third-party costs, which we track on an individual product candidate basis after a clinical product candidate has been identified. Currently, our main clinical product candidate is detalimogene. Our indirect research and development costs are primarily personnel-related costs, facilities and other costs. Employees and infrastructure are not directly tied to any one program and are deployed across our programs. As such, we do not track these costs on a specific program basis. We utilize third party contractors for our research and development activities and CDMOs for our manufacturing activities and we do not have our own laboratory or manufacturing facilities. Research and development activities are central to our business model. Currently, the Companyâ€™s sole research and development facility is located in Montreal, Quebec, Canada. We expect that our research and development expenses will continue to increase for the foreseeable future as we progress our ongoing Phase 1/2 clinical trial for detalimogene, continue to discover and develop additional product candidates, expand our headcount and maintain, expand and enforce our intellectual property portfolio. If detalimogene or any future product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. There are numerous factors associated with the successful development and commercialization of any product candidates we may develop in the future, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development program and plans. The duration, costs, and timing of clinical studies and development of our product candidate will depend on a variety of factors, any of which could mean a significant change in the costs and timing associated with the development of our product candidate including: â€¢the scope, rate of progress, and expense of our ongoing as well as any additional clinical studies and other research and development activities we undertake; â€¢future clinical study results; â€¢uncertainties in clinical study enrollment rates; â€¢new manufacturing processes or protocols that we may choose to or be required to implement in the manufacture of our drug substance and drug product; 87 â€¢regulatory feedback on requirements for regulatory approval, as well as changing standards for regulatory approval; and â€¢the timing and receipt of any regulatory approvals. Any changes in the outcome of any of these variables with respect to the development of detalimogene or any future product candidates in nonclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any clinical trials following the applicable regulatory authorityâ€™s acceptance and clearance, we could be required to expend significant additional financial resources and time to complete clinical development than we currently expect. We may never obtain regulatory approval for any product candidates that we develop. The successful development of detalimogene or any product candidates we may develop in the future is highly uncertain. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development and commercialization of detalimogene and any other product candidates we may develop. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of detalimogene or any future product candidate, if approved. This is due to the numerous risks and uncertainties associated with product development. General and Administrative General and administrative expenses consist primarily of personnel-related expenses, including salaries, benefits, and share-based compensation expenses for personnel in executive and other administrative functions. Other significant general and administrative expenses include professional services, including legal, accounting and audit services and other consulting fees as well as facility costs not otherwise included in research and development expenses, insurance, and other operating costs. We expect that our general and administrative expenses will continue to increase in the foreseeable future as our business expands to support our continued research and development activities, including our clinical trials. These increases will likely include increased costs related to the hiring of additional personnel and fees for outside consultants, among other expenses. In addition, if we obtain regulatory approval for our current product candidate or any product candidates we may develop in the future and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities. Other (Income) Expense, Net Change in fair value of convertible debenture embedded derivative liabilities Old enGeneâ€™s convertible debentures consisted of a debt instrument, a minimum interest obligation, and a share conversion feature. Old enGene identified embedded derivatives related to share conversion features within the convertible notes that required bifurcation as a single compound derivative instrument and were classified as liabilities on our consolidated balance sheets. The convertible debenture embedded derivative liabilities were initially recorded at fair value upon the date of issuance using a probability weighted expected return model and were subsequently remeasured to fair value at each reporting date. The estimated probability and timing of underlying events triggering the conversion features contained within the convertible debentures are inputs used to determine the estimated fair value of the embedded derivative. Changes in the fair value of the convertible debenture embedded derivative liabilities were recognized in change in fair value of convertible embedded derivative liabilities as a component of other expense in our consolidated statements of operations and comprehensive loss. Upon the close of the Reverse Recapitalization, Old enGeneâ€™s convertible debentures were exchanged for Common Shares of the Company, or settled through repayment, resulting in an extinguishment of the convertible debentures and related embedded derivative liabilities. Change in fair value of warrant liabilities Old enGene issued warrants to purchase redeemable convertible preferred shares as part of the issuance of certain redeemable convertible preferred shares and convertible debentures. Old enGene accounted for the redeemable convertible preferred shares warrants issued based upon the characteristics and provisions of the instrument and determined that the warrants were liability classified. The redeemable convertible preferred share warrants were recognized at their fair value on the date of issuance and remeasured to fair value at each reporting period, with the changes in fair value recognized in the change in fair value of warrant liabilities as a component of other expense in our consolidated statements of operations and comprehensive loss. Upon the close of the Reverse Recapitalization, the preferred share warrants were surrendered for no consideration and the fair value was determined to be zero. The warrants issued by Old enGene as part of the 2023 Financing (as defined herein) (the â€œ2023 Warrantsâ€) were concluded to be freestanding, liability classified instruments upon issuance, which were subsequently reclassified to equity upon the consummation of the Reverse Recapitalization. The fair value of the 2023 Warrants was estimated based on the underlying quoted market price of the FEAC public warrants, prior to the close of the Reverse Recapitalization. The 2023 Warrants were classified as a Level 2 measurement given they were substantially similar to FEAC public warrants. The 2023 Warrants were initially measured at fair value and were 88 subsequently remeasured at fair value with any changes in fair value recorded as a component of other expense in our consolidated statements of operations and comprehensive loss, so long as they remain liability classified. Upon the execution of the PIPE Financing and consummation of the Reverse Recapitalization, the 2023 Warrants were reclassified to equity as the number of warrants became fixed and it was determined that the warrants met the fixed for fixed criteria that is required for a contract to be considered indexed to the Companyâ€™s own stock as prescribed by Accounting Standards Codification (â€œASCâ€) 815, Derivatives and Hedging. Change in fair value of convertible debentures Old enGene issued convertible debentures and warrants in 2023 for which the fair value option of accounting was elected for the convertible debentures. The convertible debentures were initially recorded at fair value upon the date of issuance using a probability weighted expected return model and were subsequently remeasured to fair value at each reporting date. The estimated probability and timing of underlying events triggering the conversion contained within the convertible debentures are inputs used to determine the estimated fair value of the notes during the year ended October 31, 2023. Changes in the fair value of the convertible debentures were recognized in change in fair value of convertible debentures as a component of other expense in our consolidated statements of operations and comprehensive loss. Upon the close of the Reverse Recapitalization, convertible debentures were exchanged for Common Shares of the Company, resulting in an extinguishment of the convertible debentures. Interest Expense Interest expense is made of interest paid on our convertible notes and third-party debt, as well as non-cash interest expense for amortization of our debt discounts. Interest Income Interest income is associated with our interest-bearing cash and cash equivalents and marketable securities. Other expense, net Other expense, net primarily consists of foreign exchange gains and losses. Loss on extinguishment of convertible debentures Loss on extinguishment of convertible debentures consists of the differences between the carrying value of Old enGeneâ€™s convertible debentures and the fair value of the settlement amounts upon repayment of the convertible debentures and exchange of the convertible debentures into shares of the Company. Income Taxes Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each period or for deductible temporary differences, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. As of October 31, 2024 and 2023, we have recorded a full valuation allowance against our deferred tax assets. 89 Results of Operations Comparison of the Years Ended October 31, 2024 and 2023 The following table summarizes our results of operations for each of the periods presented (in thousands): Â Â Year Ended October 31, Â Â Â Â Â 2024 Â Â 2023 Â Â Change Â Operating expenses: Â Â Â Â Â Â Â Â Â Research and development Â $ 38,315 Â Â $ 16,458 Â Â $ 21,857 Â General and administrative Â Â 23,982 Â Â Â 9,602 Â Â Â 14,380 Â Total operating expenses Â Â 62,297 Â Â Â 26,060 Â Â Â 36,237 Â Loss from operations Â Â 62,297 Â Â Â 26,060 Â Â Â 36,237 Â Other (income) expense, net: Â Â Â Â Â Â Â Â Â Change in fair value of convertible debentureÂ Â Â embedded derivative liabilities Â Â â€” Â Â Â 21,421 Â Â Â (21,421) Change in fair value of warrant liabilities Â Â â€” Â Â Â (10,849) Â Â 10,849 Â Change in fair value of convertible debentures Â Â â€” Â Â Â 56,212 Â Â Â (56,212) Interest income Â Â (10,413) Â Â (1,117) Â Â (9,296) Interest expense Â Â 2,798 Â Â Â 4,953 Â Â Â (2,155) Loss on extinguishment and modifications ofÂ Â Â debentures Â Â â€” Â Â Â 3,091 Â Â Â (3,091) Gain on extinguishment of debt Â Â 366 Â Â Â â€” Â Â Â 366 Â Other expense, net Â Â 113 Â Â Â 129 Â Â Â (16) Total other (income) expense, net Â Â (7,136) Â Â 73,840 Â Â Â (80,976) Net loss before income tax Â Â 55,161 Â Â Â 99,900 Â Â Â (44,739) Provision for (recovery of) income tax Â Â (19) Â Â 17 Â Â Â (36) Net loss Â $ 55,142 Â Â $ 99,917 Â Â $ (44,775) Â Research and Development Expenses The following table summarizes our research and development expenses for each of the periods presented (in thousands): Â Â Â Year Ended October 31, Â Â Â 2024 Â Â 2023 Â Â Change Â Direct costs: Â Â Â Â Â Â Â Â Â Detalimogene Â $ 24,772 Â Â $ 7,965 Â Â $ 16,807 Â Preclinical programs Â Â 762 Â Â Â 620 Â Â Â 142 Â Total direct research and development expenses Â Â 25,534 Â Â Â 8,585 Â Â Â 16,949 Â Indirect costs: Â Â Â Â Â Â Â Â Â General research and platform personnel related costs Â Â 11,155 Â Â Â 6,350 Â Â Â 4,805 Â Unallocated laboratory, facility support and patent costs Â Â 1,626 Â Â Â 1,523 Â Â Â 103 Â Total indirect research and development expenses Â Â 12,781 Â Â Â 7,873 Â Â Â 4,908 Â Total research and development expenses Â Â 38,315 Â Â Â 16,458 Â Â Â 21,857 Â Research and development expenses increased by $21.9 million from $16.5 million for the year ended October 31, 2023 to $38.3 million for the year ended October 31, 2024. This increase was attributable to the following: â€¢a $16.8 million increase in detalimogene direct expense is a result of our increasing clinical and manufacturing activities to advance our LEGEND study of detalimogene in BCG-unresponsive NMIBC, and prepare for our planned Biologics License Application submission; and â€¢a $4.8 million increase in personnel-related costs primarily due to an increase in share-based compensation expenses and in employee headcount. Included within personnel-related costs is $1.8 million and $0.8 million of share-based compensation, for the years ended October 31, 2024 and 2023, respectively. 90 General and Administrative Expenses The following table summarizes our general and administrative expenses for each of the periods presented (in thousands): Â Â Year Ended October 31, Â Â Â Â Â 2024 Â Â 2023 Â Â Change Â Personnel-related expenses Â $ 12,344 Â Â $ 4,780 Â Â $ 7,564 Â Professional fees Â Â 7,443 Â Â Â 3,297 Â Â Â 4,146 Â Patent maintenance and legal fees Â Â 1,879 Â Â Â 1,132 Â Â Â 747 Â Other expenses Â Â 2,316 Â Â Â 393 Â Â Â 1,923 Â Total general and administrative expenses Â $ 23,982 Â Â $ 9,602 Â Â $ 14,380 Â Â General and administrative expenses increased by $14.4 million from $9.6 million for the year ended

October 31, 2023 to $24.0 million for the year ended October 31, 2024. This increase was primarily attributable to the following: â€¢a $7.6 million increase in personnel-related expenses primarily driven by share-based compensation expense and in employee headcount. Included within personnel-related costs is $3.5 million and $2.6 million of share-based compensation, for the years ended October 31, 2024 and 2023, respectively; â€¢a $4.1 million increase in costs related to professional fees primarily driven by accounting and audit related fees; and â€¢a $1.9 million increase in other expenses driven by directors and officers' insurance expense as a result of operating as a public company. Other (Income) Expense, Net Other (income) expenses, decreased by approximately $81.0 million from expense of $73.8 million for the year ended October 31, 2023 to income of $7.1 million for the year ended October 31, 2024. This increase is attributable to a $9.3 million increase in interest income earned in the current period from larger cash balances arising from the February 2024 PIPE Financing and the October 2024 PIPE Financing (collectively, the â€œ2024 PIPE Financingsâ€), a $2.2 million decrease in interest expense as expense associated with the conversion and repayments of our convertible debentures were no longer applicable to the current period (only interest expense that was incurred related to the debt facility with Hercules Capital in the current period), a $66.8 million net expense from the change in fair value of warrant and convertible debt liabilities during the year ended October 31, 2023 that were no longer applicable to the current period as the associated instruments were settled upon the close of the Reverse Recapitalization, and a $3.1 million loss on extinguishment of debt during the year ended October 31, 2023 as compared to $0.4 million gain on extinguishment of debt that was incurred during the current year. Liquidity and Capital Resources Sources of Liquidity Since our inception, we have incurred significant losses in each period and on an aggregate basis. We have not yet commercialized any product candidates, and we do not expect to generate revenue from sales of any product candidates or from other sources for several years, if at all. As of October 31, 2024, we had $173.0 million in cash and cash equivalents and $124.9 million in marketable securities, and we had an accumulated deficit of $254.7 million. Since the Reverse Recapitalization, we have financed our operations primarily through proceeds received through PIPE financings and debt facility with Hercules. Our recent sources of liquidity include the $200.0 million from the February 2024 PIPE Financing, net of issuance costs of $12.4 million, and the $60.1 million from the October 2024 PIPE Financing, net of issuance costs of $3.8 million. Based on our current operating plans, we expect our cash and cash equivalents as of October 31, 2024 will be sufficient to fund the Companyâ€™s operating expenses and debt obligations requirements for at least the next 12 months from the issuance date of the consolidated financial statements included within this Annual Report, without giving effect to any potential milestone debt tranches we may be eligible to drawdown further under our debt facility with Hercules. Our current operating plan is based on various assumptions. If we use our capital resources sooner than expected, we will evaluate reductions in expense or obtaining additional financing. This may include pursuing a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. There can be no assurance that such financing will be available in sufficient amounts or on acceptable terms, if at all, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations. Â 91 Cash Flows Comparison of the years ended October 31, 2024 and 2023 The following table provides information regarding our cash flows for each of the periods presented (in thousands): Â Â Year Ended October 31, Â Â 2024 Â Â 2023 Â Net cash used in operating activities Â $ (48,281) Â $ (24,743) Net cash used in investing activities Â Â (125,953) Â Â (318) Net cash provided by financing activities Â Â 265,716 Â Â Â 86,147 Â Effect of exchange rate changes on cash Â Â 1 Â Â Â 1 Â Net increase in cash and cash equivalents Â $ 91,483 Â Â $ 61,087 Â Â Net Cash Used in Operating Activities Net cash used in operating activities for the fiscal year ended October 31, 2024 was $48.3 million and was primarily due to our net loss of $55.1 million, partially offset by adjustments for non-cash charges totaling $6.8 million. Further changes were driven by the receipt of a $2.0 million refundable investment tax credit and a $1.9 million increase in other net working capital adjustments. Net cash used in operating activities for the fiscal year ended October 31, 2023 was $24.7 million and was primarily due to our net loss of $99.9 million, partially offset by adjustments for non-cash charges totaling $75.7 million. Further changes were driven by a $1.0 million increase in investment tax credit receivables and a $0.5 million decrease in other net working capital adjustments. Net Cash Used in Investing Activities Net cash used in investing activities for each of the fiscal years ended October 31, 2024 and 2023 was $125.9 million and $0.3 million, respectively, consisting of purchases of marketable securities during the current year and property and equipment during each year. Net Cash Provided by Financing Activities Net cash provided by financing activities for the fiscal year ended October 31, 2024 was $265.7 million, primarily resulting from $260.1 million received from the 2024 PIPE Financings, which were partially offset by issuance costs of $12.4 million, $22.5 million received from the Term Loan (as defined herein), which was offset by $9.4 million in principal repayments of the Prior Term Loan, $6.1 million from exercise of common share warrants and stock options, offset by $0.6 million in debt issuance costs paid as part of the Term Loan, and $0.6 million of SPAC transaction costs paid to FEAC in connection with the Reverse Recapitalization. Net cash provided by financing activities for the fiscal year ended October 31, 2023 was $86.1 million, resulting from proceeds of $38.0 million received from the issuance of convertible debentures, and $64.3 million gross proceeds received from the PIPE Financing and Reverse Recapitalization, partially offset by the repayment of scheduled principal payments of the Hercules term loan of $1.6 million, full repayment of the BDC convertible debentures of $3.2 million, payment of debt issuance costs of $0.9 million and payment of transaction costs in connection with the Reverse Recapitalization and PIPE Financing of $10.5 million. Hercules Loan Agreement On December 30, 2021, we entered into a Loan and Security Agreement (the â€œPrior Loan Agreementâ€) with Hercules for the issuance of a term loan facility of an aggregate principal amount of up to $20.0 million (the â€œPrior Term Loanâ€). The Prior Loan Agreement has remained in place after the consummation of the Reverse Recapitalization, until its amendment and restatement in December 2023, as discussed below. The Prior Loan Agreement provided for (i) an initial term loan advance of $7.0 million, which closed on December 30, 2021, (ii) subject to the achievement of certain Clinical Milestones (the â€œClinical Milestoneâ€), a right of the Company to request that the Lender make additional term loan advances to us in an aggregate principal amount of up to $4.0 million from the achievement of the Clinical Milestone through June 15, 2022, which was drawn in June 2022, and (iii) subject to the achievement of certain financial milestones (the â€œFinancial Milestoneâ€), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $9.0 million from achievement of the Financial Milestone through December 15, 2022, which was not achieved. We were required to pay an end of term fee (the â€œPrior Term Loan End of Term Chargeâ€) equal to 6.35% of the aggregate principal amount of the Prior Term Loans advances upon repayment. The financing agreement contained negative covenants that, among other things and subject to certain exceptions, could have restricted our ability to incur additional liens, incur additional indebtedness, make investments, including acquisitions, engage in fundamental changes, sell or dispose of assets that constitute collateral, including certain intellectual property, pay dividends or make any distribution or payment on or redeem, retire or purchase any equity interests, amend, modify or waive certain material agreements or organizational documents and make payments of certain subordinated indebtedness. 92 The Prior Term Loan was scheduled to mature on July 1, 2025, with no option for extension (the â€œPrior Term Loan Maturity Dateâ€). Under the Prior Loan Agreement, Old enGene agreed to issue to Hercules warrants (the â€œOld Hercules Warrantsâ€) to purchase a number of shares of Old enGeneâ€™s redeemable convertible preferred shares at the exercise price equal to 2.5% of the aggregate amount of the Prior Term Loans that are funded, as such amounts are funded. Old enGene issued a total of 133,692 warrants to purchase Class C redeemable convertible preferred shares. Upon the close of the Reverse Recapitalization, the Old Hercules Warrants, along with all other warrants to purchase shares of Old enGene's redeemable convertible preferred shares, were surrendered for no consideration. Amended Loan and Security Agreement On December 22, 2023 (the â€œHercules Closing Dateâ€), we entered into an amended and restated loan and security agreement (the â€œAmended Loan Agreementâ€), with Hercules, as agent and lender, and the several banks and other financial institutions or entities from time to time parties thereto (with Hercules, the â€œLendersâ€). The Amended Loan Agreement amends and restates in its entirety the Prior Loan Agreement with Hercules dated December 30, 2021. As of October 31, 2024, the Amended Loan Agreement provides for a term loan facility of up to $50.0 million available in multiple tranches (the â€œTerm Loanâ€), as follows: (i) an initial term loan advance (the â€œTranche 1 Advanceâ€) that was made on the Hercules Closing Date of $22.5 million, approximately $8.6 million of which was applied to refinance in full the term loans outstanding under the Prior Loan Agreement, (ii) subject to the achievement of the specified interim milestone (the â€œInterim Milestoneâ€) and satisfaction of certain other conditions precedent, our right to request that the Lenders make additional term loan advances to us in an aggregate principal amount of up to $7.5 million from the achievement of the Interim Milestone through the earlier of (x) 60 days following the Interim Milestone and (y) March 31, 2025, and (iii) an uncommitted tranche subject to the Lendersâ€™ investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which we may request from time to time up to and including the Amortization Date (as defined below) that the Lenders make additional term loan advances to us in an aggregate principal amount of up to $20.0 million. We are required to pay upon the earlier of January 1, 2028 (the â€œMaturity Dateâ€) or payment in full of the Term Loans, an end of term fee equal to 5.50% of the aggregate principal amount of the Term Loans (the â€œEnd of Term Chargeâ€). We are also required to pay on July 1, 2025 or, if earlier, the date we prepay the Term Loans, approximately $0.7 million representing the Prior Term Loan End of Term Charge (the Prior Term Loan End of Term Charge and End of Term Charge, collectively the â€œEnd of Term Chargesâ€). The Term Loans mature on January 1, 2028, with no option for extension. The Term Loan bears cash interest payable monthly at an annual rate equal to the greater of (a) the prime rate of interest as reported in the Wall Street Journal plus 0.75% (capped at 9.75%) and (b) 9.25%. The Term Loan also bears additional payment-in-kind interest at an annual rate of 1.15%, which is added to the outstanding principal balance of the Term Loan on each monthly interest payment date. Borrowings under the Amended Loan Agreement are repayable in monthly interest-only payments through the â€œAmortization Dateâ€, which is either: (x) July 1, 2025 or (y) if the Interim Milestone is achieved and there has been no default, January 1, 2026, or (z) if the Interim Milestone and certain clinical milestones are achieved and there has been no default under the Amended Loan Agreement, July 1, 2026. After the Amortization Date, the outstanding Term Loans and interest shall be repayable in equal monthly payments of principal and accrued interest until the Maturity Date. At our option, we may elect to prepay all, but not less than all, of the outstanding Term Loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% of the principal amount outstanding if the prepayment occurs in any of the first twelve months following the Hercules Closing Date; (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the Hercules Closing Date but on or prior to twenty-four months following the Hercules Closing Date; and (iii) 1.0% of the principal amount outstanding if prepayment occurs at any time thereafter but prior to the Maturity Date. In connection with the Amended Loan Agreement, we granted Hercules a security interest senior to any current and future debts and to any security interest in all of our right, title, and interest in, to and under all of our property and other assets, subject to limited exceptions including our intellectual property. The Amended Loan Agreement contains negative covenants that, among other things and subject to certain exceptions, could restrict our ability to incur additional liens, incur additional indebtedness, make investments, including acquisitions, engage in fundamental changes, sell or dispose of assets that constitute collateral, including certain intellectual property, pay dividends or make any distribution or payment on or redeem, retire or purchase any equity interests, amend, modify or waive certain material agreements or organizational documents and make payments of certain subordinated indebtedness. The Amended Loan Agreement also contains certain events of default and representations, warranties and non-financial covenants of ours. We have been in compliance with the financial covenants and non-financial covenants since inception of the Term Loan. We accounted for the Amended Loan Agreement as an extinguishment of the Prior Term Loan. As a result of the extinguishment, we recorded a loss of $0.4 million as a component within other income and expense in our consolidated statement of 93 operations during the year ended October 31, 2024, which represented the reacquisition price of the debt, including fees and the initial fair value of the warrants to the Lender, and the carrying value of the Prior Term Loan at the time of extinguishment. As of October 31, 2024, we had outstanding borrowings of $22.5 million under the Amended Loan Agreement and incurred $2.2 million of debt discount and issuance costs inclusive of legal fees and End of Term Charges under the Term Loan. In connection with the Amended Loan Agreement, we also agreed to issue to the Lenders in connection with each advance of Term Loans warrants to purchase that number of our Common Shares as shall be equal to 2% of the aggregate principal amount of such Term Loan advance divided by the Warrant per share exercise price of $7.21 (which exercise price equals the ten-day volume weighted average price for the ten (10) trading days immediately preceding the Hercules Closing Date and is subject to customary adjustments under the terms of the Warrants) (the â€œHercules Common Share Warrantsâ€). The Hercules Common Share Warrants are exercisable for a period of seven years from issuance. On the Hercules Closing Date, we issued to the Lenders 62,413 Hercules Common Share Warrants in connection with the Tranche 1 Advance of the Term Loan. Under the terms of the Amended Loan Agreement, the maximum number of Hercules Common Share Warrants and underlying Common Shares of the Company that could be issued is 138,696. As of October 31, 2024 and October 31, 2023 the carrying value of the note payable consists of the following (in thousands): Â Â Â Year Ended October 31, Â Â Â 2024 Â Â 2023 Â Note payable, including End of Term Charge Â $ 24,663 Â Â $ 10,144 Â Debt discount, net of accretion Â Â (1,673) Â Â (474) Accrued interest Â Â 182 Â Â Â 108 Â Note payable, net of discount Â $ 23,172 Â Â $ 9,778 Â Â Â During the fiscal years ended October 31, 2024 and 2023, the Company recognized $2.2 million and $1.8 million of interest expense related to the Loan Agreement, respectively. Â As of October 31, 2023, the Company classified $0.6 million of the note payable as current, which represents the principal payments due and amortization of the debt discount between October 31, 2023 and the date the Term Loan was amended in December 2023 (see below). Subsequent to the amendment to the Term Loan, we are not required to make any principal payments until at least July 1, 2025. Estimated future principal payments due under the Term Loan, including the contractual End of Term Charges and payment-in-kind interest as of October 31, 2024 are as follows: Â 2025 Â $ 699 Â 2026 Â Â 8,417 Â 2027 Â Â 10,987 Â 2028 Â Â 5,161 Â Total principal payments, including End of Term Charge Â $ 25,264 Â Â The Hercules Term Loan is our only outstanding debt instrument at October 31, 2024. First Amendment to Amended and Restated Loan and Security Agreement On December 18, 2024, the Company entered into the First Amendment to Amended and Restated Loan and Security Agreement with Hercules, which amended the Amended Loan Agreement. See â€œNotes to the Financial Statementsâ€”Note 19, Subsequent Eventsâ€ for additional information. Funding Requirements Our primary uses of capital are, and we expect will continue to be, research and development activities, compensation and related expenses and general overhead costs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Based on our current operating plan, we believe that our cash on hand is sufficient to fund our operations for at least the next 12 months from the date of issuance of our consolidated financial statements included in this Annual Report. We could use our available 94 capital resources sooner than we currently expect. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on, and could increase significantly as a result of many factors, including: â€¢the initiation, timing, costs, progress and results of our planned clinical trials of detalimogene and any other product candidates we develop; â€¢the scope, progress, results and costs of our earlier-stage research programs, including the progress of preclinical development and possible clinical trials; â€¢the scope, progress, results and costs of our research programs and preclinical development of any future product candidates we may pursue; â€¢the cost of regulatory submissions and timing of regulatory approvals; â€¢the progress of the development efforts of parties with whom we may in the future enter into collaborations and/or research and development agreements; â€¢the timing and amount of milestone and other payments we are obligated to make under our Nature Technology Corporation Agreement or any future license agreements; â€¢the cash requirements of any future acquisitions or discovery of product candidates; â€¢our ability to establish and maintain collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all; â€¢the costs to acquire or in-license any products, product candidates or technologies; â€¢the costs associated with maintaining, expanding and protecting our intellectual property portfolio, including costs involved in prosecuting and enforcing patent and other intellectual property claims; â€¢the costs of manufacturing detalimogene and any other product candidates we develop by third parties; â€¢the cost of establishing commercial launch capabilities in anticipation of a potential regulatory approval of detalimogene or any other product candidates we develop; â€¢the cost of commercialization activities if detalimogene or any future product candidates we develop are approved for sale, including marketing, sales and distribution costs ; â€¢our efforts to add operational, financial and management information systems, enhance existing operational, financial and management information systems and hire additional personnel, including personnel to support development of our product candidates, commercial launch preparation and commercialization efforts and our other operations as a public company; and â€¢the costs of operating as a public company. A change in the outcome of any of these or other variables with respect to the development of our lead candidates or any product or development candidate we may develop in the future could significantly change the costs and timing associated with our development plans. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans. Old enGene was eligible to claim Canadian federal and provincial tax credits as a Canadian controlled private corporation (â€œCCPCâ€) on eligible scientific research and experimental development (â€œSR&EDâ€) expenditures through September 2023, at which time the Company lost its status as a CCPC in connection with the Reverse Recapitalization. As such, the Company is no longer eligible for cash refunds on federal tax credits earned with respect to federally eligible SR&ED expenditures. Following the loss of CCPC status, the Companyâ€™s federal SR&ED tax credits are earned at a lower rate and may only be used to offset future federal taxes payable. Provincial tax credits earned in QuÃ©bec in relation to SR&ED expenditures are anticipated to continue to result in a cash refund to the Company, albeit at a reduced rate. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, which could include collaborations, strategic alliances or licensing arrangements. Adequate additional financing, if available, may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing shareholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such shareholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely 95 impact our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research program or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Because of the numerous risks and uncertainties associated with product development, there is no assurance that we will ever be profitable or generate positive cash flow from operating activities. Contractual Obligations and Other Commitments License Agreement with Nature Technology Corporation On April 10, 2020, we entered into the License Agreement with NTC pursuant to which NTC granted us a worldwide non-exclusive, royalty-bearing and sublicensable license to certain patents and know-how relating to the Nanoplasmidâ„¢ vector backbone that is used in detalimogene voraplasmid to research, develop, make, use, import, sell and offer and sell, any gene and cell therapy products incorporating the Nanoplasmidâ„¢ vector backbone (excluding any such products in the field of dermatology). Unless terminated earlier, the License Agreement will continue until no valid claim of any licensed patent exists in any country. We can voluntarily terminate the License Agreement with prior notice to NTC. We paid NTC an initial, upfront fee of $50 thousand which was recorded as research and development expense upon entering into the License Agreement. Beginning on the first anniversary of the effective date of the License Agreement and on each subsequent anniversary, we are required to pay NTC a $50 thousand annual maintenance fee until the first sale of a product for which a royalty is due. We are also required to make a payment to NTC of $50 thousand upon assigning the License Agreement to a third-party. The License Agreement provides for a one-time payment of $50 thousand for the first dose of a product covered by a valid claim of a licensed patent (a â€œMilestone Productâ€) in the first patient in a Phase 1 clinical trial or, if there is no Phase 1 clinical trial, in a Phase 2 clinical trial, as well as a one-time payment of $450 thousand upon regulatory approval of a Milestone Product by the U.S. Food and Drug Administration. The first milestone related to the first dose of a Milestone Product, was achieved during the year ended October 31, 2021. The second milestone, regulatory approval of a Milestone Product, has not yet been achieved as of the year ended October 31, 2024. We are also required to pay NTC a royalty percentage in the low single digits of the aggregate net product sales in a calendar year by us, our affiliates or sublicensees on a product-by-product and country-by-country basis, as long as the composition or use of the applicable product is covered by a valid claim in the country where the net sales occurred. Royalty obligations under the License Agreement will continue until the expiration of the last valid claim of a licensed patent covering such licensed product in such country. In the event that we or any of our affiliates or sublicensees manufactures any GMP lot of a licensed product, then we or any such affiliate or sublicensee will be obligated to pay NTC an amount per manufactured gram of GMP (or its equivalent) lot of product, which varies based on the volume manufactured. Such manufacturing payment will expire on a product-by-product basis upon receipt of regulatory approval to market a product in any country in the licensed territory. For a more detailed description of this agreement, see â€œItem 1. Businessâ€”Intellectual Propertyâ€”Strategic License Agreementâ€ and â€œNotes to the Financial Statementsâ€—Note 8, License Agreement and Clinical Research Organizationâ€ included elsewhere in this Annual Report. Lease Obligations Our leases are comprised of all operating leases for office and lab space. We have a month-to-month office and lab space lease located in Montreal, Quebec, Canada, which commenced in November 2021 and had an initial term of 12 months that expired on October 31, 2022. The lease includes options to renew for consecutive twelve-month periods upon landlord consent, at new lease rates. In October 2022, we entered into a lease amendment to extend the lease for an additional term of six months through April 2023, with an option to extend the lease through September 2023. In April 2023, the Company extended the lease through September 2023. In September 2023, the Company extended the lease term through November 5, 2023. The amendment resulted in $0.2 million of additional lease commitments to be paid during the extended term, inclusive of the extension through November 5, 2023. On December 29, 2022, we signed a new lease for approximately 10,620 square feet of new laboratory and office space at 4868 Rue Levy, Montreal, QC. The term of the lease is for 10 years beginning on the commencement date and requires an annual initial base rent of $36.50 Canadian Dollar (â€œCADâ€) per square foot, which is subject to annual increases of 2%. The lease commenced in November 2023. On January 1, 2024, we entered into a lease agreement, in which we are sub-leasing approximately 6,450 square feet of office space located at 200 Fifth Avenue, Waltham, Massachusetts 02451. We will make an aggregate amount of base rental payments of $0.5 million, under the initial term of the lease, which is set to expire on December 30, 2026 and does not have an option to renew. 96 Purchase and Other Obligations We enter into contracts in the normal course of business with CROs, CDMOs and other third-party vendors for nonclinical research studies and testing, clinical trials and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including those incurred by subcontractors of our suppliers. The Company does not have material capital expenditure commitments at October 31, 2024. Critical Accounting Estimates for the years ended October 31, 2024 and 2023 This managementâ€™s discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make judgments and estimates that affect the reported amounts of assets, liabilities and expenses, as well as related disclosures during the reported periods. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the financial statements prospectively from the date of change in estimates. While our accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report, we believe the following accounting policies used in the preparation of our financial statements require the most significant judgments and estimates. Accrued and Prepaid Research and Development Expenses As part of the process of preparing our financial statements, we are required to estimate our accrued and prepaid third-party research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued and prepaid expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued and prepaid research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. Share-Based Compensation We measure all share-based awards granted to employees, officers, directors and non-employees based on the fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Our share-based payments related only to stock options issued to date. We account for forfeitures of our share-based awards as they occur. We have historically issued share-based awards with only service-based vesting conditions. In July 2023, we issued 1,046,764 stock options which have performance conditions tied to the closing of the Reverse Recapitalization and the filing of an effective registration statement. For share-based awards with service-based vesting conditions, we record the expense using the straight-line method including when such awards have graded vesting. For performance-based awards, we record the expense when achievement of the performance condition is deemed probable using an accelerated attribution method, as if each vesting tranche was treated as an individual award. For all stock options granted at fair value of the underlying Common Shares at the time of the grant with service-based vesting, the fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs 97 based on certain subjective assumptions, including the fair value of our Common Shares (prior to the Reverse Recapitalization) expected share price volatility, the expected term of the award, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. We determine the volatility for awards granted based on an analysis of reported data for a group of guideline companies that have issued options with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. The expected option term for share-based awards with only service-based vesting was calculated based on the simplified method, which uses the midpoint between the vesting date and the contractual term, as we do not have sufficient historical data to develop an estimate based on participant behavior. The expected option term for performance-based awards has been determined considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, and comparison to expected terms used by peers. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. We have not paid, and do not anticipate paying, cash dividends on our Common Shares; therefore, the expected dividend yield is assumed to be zero. Prior to the Reverse Recapitalization, because there was no public market for Old enGeneâ€™s common shares, its Board of Directors approved the fair value of its common share based on third-party valuations of its common shares. Initially, the enterprise equity value of Old enGene was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Companyâ€™s various securities of its capital structure using an option pricing method, or OPM, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another. Significant assumptions used in the OPM to determine the fair value of common shares include volatility, discount for lack of marketability, and the expected timing of a future liquidity event such as an initial public offering, or sale of our Company in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios. In addition, various objective and subjective factors were considered to determine the fair value of our Common Shares as of each grant date of stock options, including, among other factors: â€¢the prices at which we sold shares of preferred shares and the superior rights and preferences of the preferred shares relative to its Common Shares at the time of each grant, â€¢the estimated value of each security both outstanding and anticipated, â€¢the anticipated capital structure that will directly impact the value of the currently outstanding securities, â€¢our financial position, including cash on hand, and our historical and forecasted performance and operating results, â€¢the progress of our research and development programs, â€¢our stage of development and business strategy and the material risks related to our business and industry, â€¢the likelihood of achieving a liquidity event for the holders of our Common Shares, such as an initial public offering or a sale of our Company, given prevailing market conditions, â€¢external market conditions affecting the biotechnology industry sectors, â€¢local and global economic conditions, and â€¢the lack of an active public market for our Common Shares and redeemable convertible preferred shares. The assumptions underlying these valuations represented managementâ€™s best estimate, which involved inherent uncertainties and the application of managementâ€™s judgment and these valuations are sensitive to changes in the unobservable inputs. As a result, if we had used different assumptions or estimates, or if there are changes to the unobservable inputs, the fair value of its Common Shares and share-based compensation expense could have been materially different. Subsequent to the consummation of the Reverse Recapitalization, the fair value of the Common Shares used in the Black-Scholes option-pricing model to determine the fair value of the stock option will be determined based on the quoted price of our Common Shares. Further, there were no performance conditions outstanding subsequent to the consummation of the Reverse Recapitalization. Our share-based compensation expense is recorded in general and administrative and research and development expenses in the Companyâ€™s consolidated statements of operations and comprehensive loss. We recorded share-based compensation expense of $5.3 million and $3.5 million for the fiscal years ended October 31, 2024 and 2023, respectively. Old enGeneâ€™s Board of Directors granted 1,046,764 options to employees on July 7, 2023 for non-voting common shares of Old enGene at an exercise price of $5.87 CAD ($4.24 USD). The exercise price of $5.87 CAD ($4.24 USD) was approved by Old enGene's Board of Directors and determined to be equal to the fair value of its common shares on the grant date based on a valuation performed by an independent third-party valuation specialist and considering (i) the lapse of time between the date of the valuation as of May 31, 2023 and the grant of the award was limited, and (ii) events between the valuation date and grant date that would affect the valuation of common shares. Significant assumptions used in the valuation to determine the fair value of common shares included expected value of common shares, discount rate, DLOM, and the expected timing of a future liquidity event such as an initial public offering, SPAC transaction or sale of Old enGene, in light of prevailing market conditions. These options were not exercisable unless and until the 98 completion of the Merger Agreement and there was an effective registration statement for the shares underlying such granted options and the options would have terminated automatically in the event of the termination of the Merger Agreement. We valued these awards at the grant date using Black-Scholes pricing model in which the fair value of the stock on the grant date was equal to the exercise price of the award. Upon meeting the exercisability conditions, 794,643 of the issued options were fully vested and exercisable, and the remaining 252,121 options vest over varying terms up to four years. We recognize compensation expense when achievement of the performance condition is deemed probable using an accelerated attribution method, as if each vesting tranche was treated as an individual award. C-Level Transition Agreements On February 13, 2024, the Company (through its subsidiary, enGene USA, Inc.) entered into a Transition and Modification Agreement (the â€œTransition Agreementâ€) with the Company's former Chief Executive Officer, Jason Hanson, which amended and modified the Employment Agreement, dated November 8, 2023, between Mr. Hanson and enGene USA (the â€œHanson Employment Agreementâ€). On July 23, 2024, the Company (through its subsidiary, enGene USA, Inc.) and Mr. Hanson entered into the Amendment to Transition and Modification Agreement (the â€œTMA Amendmentâ€), which further amended the Transition Agreement. Under the terms of the Hanson Employment Agreement as amended by the Transition Agreement and TMA Amendment (the â€œAmended Employment Agreementâ€) Mr. Hanson is entitled to: (i) twelve months of continued health insurance benefits; (ii) payment of a 2024 target annual bonus in the amount of $390,000, less applicable taxes and withholdings; (iii) acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination; and (iv) extension of the period to exercise his vested equity awards to three years following the later of date of termination of his employment or the date of termination of the Consulting Period (as defined below), but in no event shall the post-termination exercise period of Mr. Hansonâ€™s vested equity awards extend beyond the respective applicable term thereof. The Transition Agreement further provided that, in the event Mr. Hanson were to resign upon the appointment by the Company of a new chief executive officer, Mr. Hanson would be immediately engaged in a consulting role to provide transition services as a Senior Strategic Advisor to the Company for a period of at least six months following the effective date of resignation (the â€œConsulting Periodâ€) in exchange for a monthly fee of $25,000 for the initial six-month Consulting Period, and $500 per hour thereafter, provided that Mr. Hanson need not devote more than fifteen (15) hours per week to providing such transition services. Under the Transition Agreement, the 1,216,266 stock option awards issued to Mr. Hanson were modified to allow for an extended exercise period as described above. The modification resulted in an incremental share-based compensation expense of $1.0 million which was recorded upon the effective date of the Transition Agreement. Mr. Hansonâ€™s resignation was effective as of July 19, 2024 in connection with the Companyâ€™s appointment of a new chief executive officer. On July 20, 2024, enGene appointed Ronald H. W. Cooper as Chief Executive Officer of the Company and as director of the Company's Board of Directors. Additionally, in 2024, the Company entered into a Severance Agreement with each of three former employees, including the former Chief Medical Officer and the former Chief Scientific Officer. Under the terms of Severance Agreement, the employees are entitled to twelve months of continued pay and health insurance benefits; a payment of a 2024 target annual bonus prorated through the last day of employment, acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination and an extended expiry period, which resulted in a stock-based compensation modification. Under the terms of the severance agreements, 231,684 stock option awards were modified to allow for an extended exercise period as described above. As of October 31, 2024, the Company recognized incremental stock based compensation expense of $0.5 million related to the severance agreements. Critical Accounting Estimates for the year ended October 31, 2023 Warrant Liabilities Old enGene issued warrants to purchase shares of redeemable convertible preferred shares as part of the issuance of certain of its redeemable convertible preferred shares, convertible debentures, and term loan (the â€œPreferred Share Warrantsâ€). The fair value of the Preferred Share Warrant liabilities was estimated using a Modified Black-Scholes option-pricing model, which includes assumptions that are based on the individual characteristics of the Preferred Share Warrants on the valuation date, and assumptions related to the fair value of the underlying redeemable convertible preferred shares, expected volatility, expected life, dividends, risk-free interest rate and discount for lack of marketability (â€œDLOMâ€). Due to the nature of these inputs, the Preferred Share Warrants are considered a Level 3 liability. The weighted average expected life was estimated based on the weighting of scenarios considering the probability of different terms up to the contractual term of 10 years in light of the expected timing of a future exit event, which includes a SPAC transaction. 99 The expected volatility was determined based on an analysis of reported data for a group of guideline companies that have issued instruments with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. The risk-free interest rate is determined by reference to the Canadian Treasury yield curve in effect at the time of measurement of the warrant liabilities for time periods approximately equal to the weighted average expected life of the warrant. Old enGene did not pay any cash dividends on its redeemable convertible preferred shares; therefore, the expected dividend yield was assumed to be zero. Because there was no public market for the underlying redeemable convertible preferred shares of Old enGene, its Board of Directors determined their fair value based on third-party valuations. Initially, the enterprise equity value of Old enGene was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of Old enGene. This value was then allocated towards Old enGeneâ€™s various securities of its capital structure using an option pricing method, or OPM, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another. Significant assumptions used in the OPM to determine the fair value of preferred shares include volatility, DLOM, and the expected timing of a future liquidity event such as an initial public offering, SPAC transaction or sale of Old enGene, in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios. In addition to considering the results of these valuations, Old enGeneâ€™s Board of Directors considered various objective and subjective factors to determine the fair value of our preferred shares as of each valuation date, including the prices at which Old enGene sold redeemable convertible preferred in the most recent transactions, external market conditions, the progress its research and development programs, our financial position, including cash on hand, and our historical and forecasted performance and operating results, and the lack of an active public market for its redeemable convertible preferred shares, among other factors. As part of entering into the Merger Agreement with FEAC, the holders have agreed to surrender the preferred share warrants for no consideration immediately prior to the completion of the Reverse Recapitalization. Upon the close of the Reverse Recapitalization, the Preferred Share Warrants were surrendered for no consideration and the fair value was determined to be zero. The warrants issued by Old enGene as part of the 2023 Financing (the â€œ2023 Warrantsâ€) were concluded to be freestanding, liability classified instruments upon issuance, as they failed the fixed-for-fixed criteria that is required for a contract to be considered indexed to the Companyâ€™s own stock as prescribed by ASC 815. The terms of the warrants initially required Old enGene to issue a variable number of shares until the PIPE Financing was executed, at which time the number of warrants became fixed, and it was determined that the warrants met the fixed for fixed criteria that is required for a contract to be considered indexed to the Companyâ€™s own stock as prescribed by ASC 815. The 2023 Warrants were initially and subsequently measured at fair value with any changes in fair value recorded as a component of other income and expense within the change in fair value of warrant liabilities. Old enGene estimated the fair value of the 2023 Warrants based on the underlying quoted market price of the FEAC public warrants, prior to the close of the Reverse Recapitalization. The 2023 Warrants were classified as a Level 2 measurement given they are substantially similar to FEAC public warrants. The price used to value the 2023 Warrants as of the issuance date and immediately prior to the consummation of the Reverse Recapitalization was $0.53 and $0.74, per warrant, respectively, which represented the quoted market price of the FEAC public warrants on each date. Convertible Debentures Embedded Derivative Liabilities Old enGeneâ€™s convertible debentures contain equity conversion options and certain repayment features, that have been identified as a single compound embedded derivative requiring bifurcation from the host contract for the convertible debentures for which the fair value has not been elected. The convertible debenture embedded derivative liabilities is initially measured at fair value on issuance and is subject to remeasurement at each reporting period with changes in fair value recognized in the change in fair value of derivative liabilities, net in the consolidated statements of operations and comprehensive loss. Upon the close of the Reverse Recapitalization the 2022 Notes were exchanged for Common Shares of the Company, resulting in an extinguishment of the 2022 Notes and related embedded derivative liability, and the BDC Note was repaid in full. Old enGene estimated the fair value of the convertible debenture embedded derivative liabilities on issuance and at each reporting period using a probability weighted scenario expected return model. The estimated probability and timing of underlying events triggering the conversion and liquidity repayment features and probability of exercise of the extension features within the convertible debentures, as well as discount rates, volatility and share prices, are inputs used to determine the estimated fair value of the embedded derivative. Immediately prior to the conversion and exchange of the 2022 Notes for Common Shares of the Company upon the Reverse Recapitalization, the Company remeasured the convertible debenture embedded derivative liability using a 100% probability of conversion upon the Reverse Recapitalization and the quoted market price for FEAC's common share on October 31, 2023, which was $21.70 per share, as the fair value of the common shares. 100 Fair Value Option Old enGene elected the fair value option of accounting of ASC 825 for the April 2023 Notes and the May 2023 Notes from their issuance date in order to not have to bifurcate any embedded derivatives in accordance with ASC 815. The notes for which the fair value option of accounting is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the April 2023 Notes and May 2023 Notes, which include accrued interest, if any, are recorded as a component of other expense (income), net in the consolidated statement of operations and comprehensive loss. We have not elected to present interest expense separately from changes in fair value and therefore will not present interest expense associated with the notes. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income. During the year ended October 31, 2023, we did not record any changes in fair value related to instrument-specific credit risk. No change in fair value was recorded on the April 2023 Notes during the year ended October 31, 2023, given the close proximity between the issuance date of the notes and the repayment date. As of October 31, 2023, the April 2023 Notes are no longer outstanding. Old enGene initially estimated the fair value of the May 2023 Notes using a probability weighted scenario expected return model. The estimated probability and timing of underlying events within the convertible debentures as well as discount rates, volatility and share prices are inputs used to determine the estimated fair value of the May 2023 Notes. Due to the nature of these inputs, the May 2023 Notes initially represented a Level 3 measurement within the fair value hierarchy. Immediately prior to the conversion and exchange of the May 2023 for Common Shares of the Company upon the Reverse Recapitalization, the Company remeasured the fair value of the convertible debentures using the quoted market price for FEAC's common share on October 31, 2023, which was $21.70 per share, as the fair value of the common shares for which the May 2023 Notes were exchanged for. The assumptions underlying these valuations represented managementâ€™s best estimate, which involved inherent uncertainties and the application of managementâ€™s judgment and these valuations are sensitive to changes in the unobservable inputs. As a result, if we had used different assumptions or estimates, or if there are changes to the unobservable inputs, the fair value of the April 2023 and May 2023 Notes could have been materially different. Recoverability of Investment Tax Credits Receivable In September 2023 we lost our status as a Canadian controlled private corporation (â€œCCPCâ€) and as a result, the rates at which we can claim Canadian federal and provincial tax credits on eligible SR&ED expenditures are reduced. The Canadian federal government offers a tax incentive to companies performing research and development activities in Canada and this tax incentive can be refunded or used to reduce federal income taxes in Canada otherwise payable. Such credits, if not refunded or used in the year earned, can be carried forward for a period of twenty years. Upon the loss of our CCPC status, the federal tax credit is no longer refundable. The Quebec provincial government offers a similar refundable incentive. The investment tax credits recorded are based on managementâ€™s estimates of amounts expected to be recovered and are subject to audit by the taxation authorities, the resulting adjustments of which could be significant. Following the loss of CCPC status, and as we continue to grow and expand our research and development activities outside of Canada, we anticipate our SR&ED tax credits to decrease over time. During the fiscal years ended October 31, 2024, and 2023, we recorded $0.4 million and $1.1 million, respectively, as a reduction of research and development expense associated with SR&ED investment tax credits. We have outstanding investment tax credits receivable of $0.3 million and $2.3 million as of October 31, 2024, and 2023, respectively. Emerging Growth Company and Smaller Reporting Company Status We are an â€œemerging growth companyâ€ as defined by the JOBS Act. Section 102(b)(1) of the Jumpstart Our Business Startups Act of 2012 (the â€œJOBS Actâ€) exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply (that is, those that have not had a registration statement under the Securities Act declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected to opt out of such extended transition period. In addition, for so long as we are an emerging growth company, we are permitted and intend to take advantage of exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting. We will remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of FEACâ€™s IPO, which occurred on December 14, 2021, (b) in which we have total annual revenue of at least $1.23 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates exceeds $700 million as of the end of the prior fiscal yearâ€™s second fiscal quarter; and (2) the date on which we 101 have issued more than $1.00 billion in non-convertible debt securities during the prior three-year period. References herein to â€œemerging growth companyâ€ have the meaning associated with it in the JOBS Act. Additionally, we are a â€œsmaller reporting companyâ€ as defined in Item 10(f)(1) of Regulation S-K. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common shares held by non-affiliates exceeds $250 million as of the prior April 30, or (2) our annual revenues exceed $100 million during such completed fiscal year and the market value of our common shares held by non-affiliates exceeds $700 million as of the prior April 30. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial reporting with that of other public companies difficult or impossible. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations including regarding executive compensation. Recent Accounting Pronouncements We have reviewed all recently issued accounting pronouncements and have determined that, other than as disclosed in Note 2 to our annual consolidated financial statements included elsewhere in this Annual Report and disclosed above, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations. Off-Balance Sheet Arrangements We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC. Item 7A. Quantitative and Qualitative Disclosures About Market Risk. We are a â€œsmaller reporting companyâ€ as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 7A. Item 8. Financial Statements and Supplementary Data. Our consolidated financial statements, together with the reports of our independent registered public accounting firm, appear beginning on page F-1 of this Annual Report. 102 Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure. None. Item 9A. Controls and Procedures. Evaluation of Disclosure Controls and Procedures As of the end of the period covered by this Annual Report, management, under the supervision of and with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer and principal accounting officer), carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the â€œExchange Actâ€)) to determine whether such disclosure controls and procedures provide reasonable assurance that information to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and such information is accumulated and communicated to management, including our principal executive and principal financial officers or persons performing similar functions, as appropriate to allow timely decisions regarding disclosure. Our disclosure controls and procedures were developed through a process in which our management applied its judgment in assessing the costs and benefits of such controls and procedures, which, by their nature, can provide only reasonable assurance regarding the control objectives. You should note that the design of any system of disclosure controls and procedures is based in part upon various assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. As previously reported, in connection with our preparation and the audit of our consolidated financial statements as of and for the years ended October 31, 2023 and 2022, material weaknesses were identified, as defined under the Exchange Act, in our internal control over financial reporting, of which some continue to exist at October 31, 2024. Based on our assessment, management concluded that, as of October 31, 2024, our disclosure controls and procedures were not effective due to the material weaknesses in internal controls over financial reporting described below. Managementâ€™s Report on Internal Control Over Financial Reporting Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with U.S. GAAP. Our management, under the supervision of and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of our internal control over financial reporting based on the framework in Internal Controlâ€”Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of October 31, 2024, our internal control over financial reporting was not effective due to the unremediated material weaknesses 1, 4 and 5 described below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses identified at October 31, 2023 and 2022 related to: 1.lack of formal policies, procedures and controls related to the design of internal controls over financial reporting, including risk assessment process and control activities for certain key financial reporting processes. We did not design and maintain an effective control environment commensurate with the financial reporting requirements of a public company. This resulted in our inability to consistently design and maintain formal accounting policies, procedures and controls or establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives; 2.lack of sufficient accounting and financial reporting personnel to perform appropriate accounting analysis and review procedures; 3.lack of personnel with requisite knowledge and experience in the application of GAAP; 4.general information technology controls (â€œGITCsâ€) that were not designed appropriately. Specifically, we did not design and maintain: (i) program change management controls to ensure that program and data changes are identified, tested, authorized and implemented appropriately; (ii) user access controls to ensure appropriate segregation of duties and to adequately restrict user and privileged access to appropriate personnel; (iii) computer operations controls to ensure that processing and transfer of data, and data backups and recovery are monitored; and (iv) program development controls to ensure that new software development is tested, authorized and implemented appropriately; and 5.lack of appropriate segregation of duties in the preparation and review of account reconciliations and journal entries. Based on the remediation efforts described below, material weakness 2 and 3 have been fully remediated as of October 31, 2024. Â 103 Notwithstanding these material weaknesses, management has concluded that the Companyâ€™s audited consolidated financial statements as at October 31, 2024 and 2023 present fairly, in all material respects, the financial position of the Company, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. GAAP. These material weaknesses did not result in adjustments to the Company's previously released consolidated financial results. However, because the material weaknesses create a reasonable possibility that a material misstatement to our financial statements would not be prevented or detected on a timely basis, we concluded that as of October 31, 2024 the internal control over financial reporting was not effective. This annual report does not include an attestation report of the Companyâ€™s registered public accounting firm due to the established rules of the Securities and Exchange Commission. Remediation Efforts to Address the Material Weakness Based on the remediation efforts described below, material weaknesses 2 and 3 noted above have been fully remediated as of October 31, 2024. Substantial progress has been made related to material weaknesses 1 and 5. Remediation efforts to date include the following: â€¢we hired finance and accounting personnel with adequate experience and U.S. GAAP knowledge, including Chief Financial Officer; â€¢we established adequate review and approval processes and procedures based on roles and responsibilities of each accounting members; â€¢we are implementing a risk assessment over financial reporting controls; â€¢we are designing and implementing policy, procedures and controls around key business and financial reporting process; â€¢we are implementing new software tools with adequate set up to ensure segregation of duties; and â€¢we have engaged a professional accounting services firm to help with the documentation and assessment of our internal controls for complying with the Sarbanes-Oxley Act; While significant progress has been made to enhance our internal control over financial reporting, further testing is necessary before we can conclude full remediation to material weaknesses 1 and 5. We also require additional time to design appropriate GITCs (material weakness 4). Additional time is required to complete the remediation over ineffective policies, procedures and controls related to financial reporting, GITCs and segregation of duties to demonstrate the sustainability of these remediation actions. Â Inherent Limitations on Effectiveness of Controls Â Our management, including our Principal Executive Officer and Principal Financial Officer, concluded that, as of October 31, 2024, our disclosure controls and procedures and internal control over financial reporting were not effective at a reasonable assurance level due to the material weaknesses described above. However, our management does not expect that effective disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Changes in Internal Control Over Financial Reporting Â Changes in our internal control over financial reporting during the year ended October 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting are described above. Other than the items discussed above, there were no other changes in our internal control over financial reporting during the fourth quarter ended October 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Item 9B. Other Information. None. 104 Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections. Not applicable. PART III Certain information required by Part III is omitted from this Annual Report and will be incorporated by reference from our definitive proxy statement relating to our 2025 annual meeting of shareholders, pursuant to Regulation 14A of the Exchange Act, which we refer to as our 2025 Proxy Statement. We expect to file our 2025 Proxy Statement with the SEC within 120 days of October 31, 2024. Item 10. Directors, Executive Officers and Corporate Governance. The information required by this Item 10 of Form 10-K regarding executive compensation will be included in our 2025 Proxy Statement and, other than the information required by Item 402(v) of Regulation S-K, is incorporated herein by reference. Item 11. Executive Compensation. The information required by this Item 11 of Form 10-K regarding executive compensation will be included in our 2025 Proxy Statement and, other than the information required by Item 402(v) of Regulation S-K, is incorporated herein by reference. Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters. The information required by this Item 12 of Form 10-K regarding security ownership of certain beneficial owners and management and securities authorized for issuance under equity compensation plans will be included in our 2025 Proxy Statement and is incorporated herein by reference. Item 13. Certain Relationships and Related Transactions, and Director Independence. The information required by this Item 13 of Form 10-K regarding certain relationships and related transactions and director independence will be included in our 2025 Proxy Statement and is incorporated herein by reference. Item 14. Principal Accountant Fees and Services. The information required by this Item 14 of Form 10-K regarding principal accountant fees and services will be included in our 2025 Proxy Statement and is incorporated herein by reference. 105 PART IV Item 15. Exhibits, Financial Statement Schedules. (1)For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report, incorporated into this Item by reference. (2)Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto. (3)Exhibits: Â ExhibitNumber Description 2.1 Â Business Combination Agreement, dated May 16, 2023, by and among FEAC, enGene Inc. and enGene (incorporated by reference to Exhibit 2.1 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). â€ 3.1 Â Articles of enGene Holdings Inc. (incorporated by reference to Exhibit 3.1 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). 4.1 Â Specimen Common Share Certificate of enGene (incorporated by reference to Exhibit 4.1 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). 4.2 Â Specimen Warrant Certificate of enGene (incorporated by reference to Exhibit 4.3 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). 4.3 Â Warrant Assignment, Assumption and Amendment Agreement, dated as of October 30, 2023, among FEAC, enGene Inc., enGene and Continental Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 4.3 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 31, 2023). 4.4 Â Warrant Agreement, dated December 9, 2021, between FEAC and Continental Stock Transfer & Trust Company, as warrant agent (incorporated herein by reference to Exhibit 4.1 of FEACâ€™s Current Report on Form 8-K filed with the SEC on December 14, 2021). 4.5 Â Form of Closing Date Warrant to Purchase Common Shares of enGene Holdings Inc., pursuant to the Amended and Restated Loan and Security Agreement dated December 22, 2023 (incorporated herein by reference to Exhibit 4.1 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on December 28, 2023). 4.6 Â Description of Registrantâ€™s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (incorporated herein by reference to Exhibit 4.6 to enGeneâ€™s Annual Report on Form 10-K filed with the SEC on January 29, 2024). 10.1 Â Sponsor and Insiders Letter Agreement, dated May 16, 2023, by and among FEAC, the Sponsor, Forbion Growth Opportunities Fund I Cooperatief U.A., enGene Inc., enGene and the other parties named therein (incorporated by reference to Exhibit 10.1 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). 10.2 Â Form of Subscription Agreement (incorporated by reference to Exhibit 10.2 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). 10.3 Â Form of Subscription Agreement Side Letter Agreement (incorporated by reference to Exhibit 10.3 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). 10.4 Â Form of enGene Lock-Up Agreement (incorporated by reference to Exhibit 10.4 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). 10.5 Â Registration Rights Agreement, dated October 31, 2023, by and among enGene Holdings Inc., Forbion European Acquisition Corp. and each of the Holders identified therein (incorporated herein by reference to Exhibit 10.8 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 31, 2023). 10.6 Â Private Placement Warrants Purchase Agreement, dated December 9, 2021, by and between FEAC and the Company and the Sponsor (incorporated by reference to Exhibit 10.4 to FEACâ€™s Current Report on Form 8-K filed on December 14, 2021). 10.7 Â Non-Exclusive License Agreement, dated April 10, 2020, by and between enGene and Nature Technology Corporation (incorporated by reference to Exhibit 10.14 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). +â€ 10.8 Â Master Service Agreement, dated November 11, 2019, by and between enGene and BioAgilytix Labs, LLC (incorporated by reference to Exhibit 10.15 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). +â€ 10.9 Â Letter Agreement, dated May 16, 2023, by and among enGene, IQ, FEAC and enGene (incorporated by reference to Exhibit 10.16 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). +â€ 10.10 Â Lease Agreement, dated December 29, 2022, by and between enGene and Are-Canada No. 5 Holdings, ULC (incorporated by reference to Exhibit 10.21 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). 106 10.11 Â Waiver and Consent Letter, dated September 13, 2023, by and among FEAC, enGene Inc. and enGene Holdings Inc. (incorporated by reference to Exhibit 10.22 to enGeneâ€™s Form S-4/A Registration Statement Registration No.: 333-273851 filed with the SEC on September 26, 2023). 10.12 Â enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.20 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 31, 2023). 10.13 Â Form of Nonqualified Stock Option Grant Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.21 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 31, 2023). 10.14 Â Form of Incentive Stock Option Grant Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.22 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 31, 2023). 10.15 Â Form of Restricted Stock Award Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.23 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 31, 2023). 10.16 Â Form of Restricted Stock Unit Award Agreement under enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated herein by reference to Exhibit 10.24 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 31, 2023). 10.17 Â Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.25 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 31, 2023). 10.18 Â Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan (incorporated by reference to Exhibit 10.1 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on May 15, 2024). 10.19 Â Employment Agreement, dated November 8, 2023, by and between EnGene USA, Inc. and Jason D. Hanson (incorporated herein by reference to Exhibit 10.01 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on November 9, 2023).# 10.21 Â Employment Agreement, dated November 8, 2023, by and between EnGene USA, Inc. and James C. Sullivan (incorporated herein by reference to Exhibit 10.03 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on November 9, 2023).# 10.22 Â Employment Agreement, dated December 13, 2023, by and between enGene USA, Inc. and Ryan Daws (incorporated herein by reference to Exhibit 10.1 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on December 13, 2023).# 10.23 Â Employment Agreement, dated November 29, 2023, by and between enGene USA, Inc. and Richard Bryce (incorporated herein by reference to Exhibit 10.2 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on November 29, 2023).# 10.24 Â Transition and Modification Agreement, dated February 13, 2024 by and between enGene USA, Inc. and Jason D. Hanson (incorporated herein by reference to Exhibit 10.2 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on February 14, 2024).# 10.25 Â Employment Agreement, dated April 22, 2024, by and between enGene USA, Inc. and Lee Giguere (incorporated by reference to Exhibit 10.2 of enGeneâ€™s Quarterly Report on Form 10-Q filed with the SEC on June 14, 2024).# 10.26 Â Employment Agreement, dated July 22, 2024, by and between enGene USA, Inc. and Ronald H. W. Cooper. (incorporated herein by reference to Exhibit 10.1 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on July 24, 2024).# 10.27 Â Amendment to Transition and Modification Agreement, dated July 23, 2024 by and between enGene USA, Inc. and Jason D. Hanson (incorporated herein by reference to Exhibit 10.2 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on July 24, 2024).# 10.28 Â Employment Agreement, dated July 22, 2024, by and between enGene USA, Inc. and Raj Pruthi (incorporated herein by reference to Exhibit 10.3 of enGeneâ€™s Quarterly Report on Form 10-Q filed with the SEC on September 10, 2024).# 10.29 Â Transition Services Agreement and General Release, dated July 16, 2024, by and between enGene USA, Inc. and Richard Bryce (incorporated herein by reference to Exhibit 10.4 of enGeneâ€™s Quarterly Report on Form 10-Q filed with the SEC on September 10, 2024).# 10.30 Â Inducement Grant Agreement, dated July 22, 2024, by and between enGene Holdings Inc. and Ronald H. W. Cooper (incorporated herein by reference to Exhibit 10.5 of enGeneâ€™s Quarterly Report on Form 10-Q filed with the SEC on September 10, 2024).# 10.31 Â Amended and Restated Employment Agreement, dated October 16, 2024, by and between enGene USA, Inc. and Alexander Nichols (incorporated herein by reference to Exhibit 10.1 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 21, 2024).# 10.32* Â Amended and Restated Employment Agreement, dated October 21, 2024, by and between enGene Inc. and Anthony T. Cheung.# 10.33* Â Employment Agreement, dated October 21, 2024, by and between enGene USA, Inc. and Joan Connolly.# 10.34* Â Separation and General Release Agreement, dated October 16, 2024, by and between enGene USA, Inc. and James Sullivan.# 10.35 Â Amended and Restated Loan and Security Agreement, dated December 22, 2023, by and among enGene Holdings Inc., enGene Inc. and enGene USA, Inc., as borrower, Hercules Capital, Inc., as agent, and the lenders from time to time party thereto (incorporated by reference to Exhibit 10.1 to enGeneâ€™s Current Report on Form 8-K filed with the SEC on December 28, 2023). â€ + 10.36* Â First Amendment to Amended and Restated Loan and Security Agreement, dated December 18, 2024. â€ + 10.37 Â Form of Subscription Agreement, dated February 13, 2024 (incorporated by reference to Exhibit 10.1 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on February 14, 2024). 107 10.38 Â Form of Subscription Agreement, dated October 24, 2024 (incorporated by reference to Exhibit 10.1 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 25, 2024). 19.1* Â Insider Trading Policy. 21.1 Â Subsidiaries of the Registrant (incorporated herein by reference to Exhibit 21.1 of enGeneâ€™s Current Report on Form 8-K filed with the SEC on October 31, 2023). 23.1* Â Consent of Independent Registered Public Accounting Firm. 31.1* Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. 31.2* Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. 32.1* Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. 32.2* Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. 97.1* Â Policy Relating to Recovery of Erroneously Awarded Compensation. 101.INS Inline XBRL Instance Document â€“ the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document. 101.SCH Â Inline XBRL Taxonomy Extension Schema Document 101.CAL Â Inline XBRL Taxonomy Extension Calculation Linkbase Document 101.DEF Â Inline XBRL Taxonomy Extension Definition Linkbase Document 101.LAB Â Inline XBRL Taxonomy Extension Label Linkbase Document 101.PRE Â Inline XBRL Taxonomy Extension Presentation Linkbase Document 104 Â Cover Page Interactive Data File (embedded within the Inline XBRL document) Â * Filed herewith. â€ Certain of the exhibits and schedules to these exhibits have been omitted in accordance with Regulation S-K Item 601(a)(5). The registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request. + Portions of this exhibit are redacted in accordance with Regulation S-K Item 601(b)(10)(iv). # Indicates a management contract or compensatory plan or arrangement. Item 16. Form 10-K Summary None. 108 SIGNATURES Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized. Â enGene Holdings Inc. Date: December 19, 2024 By: /s/ Ronald H. W. Cooper Name: Ronald H. W. Cooper Title: Chief Executive Officer Â Pursuant to the requirements of the Securities Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated. Â Signature Title Â Date Â /s/ Ronald H. W. Cooper Chief Executive Officer and Director(Principal Executive Officer) Â December 19, 2024 Â Ronald H. W. Cooper Â Â Â Â /s/

Ryan Daws Chief Financial Officer(Principal Financial Officer and Principal Accounting Officer) Â December 19, 2024 Ryan Daws Â Â Â Â Â /s/ Jasper Bos Director December 19, 2024 Jasper Bos Â Â Â Â Â Â Â Â Â /s/ Gerald Brunk Â Director Â December 19, 2024 Gerald Brunk Â Â Â Â Â Â Â Â Â /s/ Dr. Richard Glickman Â Director Â December 19, 2024 Dr. Richard Glickman Â Â Â Â Â Â Â Â Â /s/ Paul Hastings Â Director Â December 19, 2024 Paul Hastings Â Â Â Â Â /s/ Wouter Joustra Â Director Â December 19. 2024 Wouter Joustra Â Â Â Â Â Â Â Â Â /s/ Lota Zoth Â Director Â December 19, 2024 Lota Zoth Â 109 Â INDEX TO FINANCIAL STATEMENTS Â Â Page Report of Independent Registered Public Accounting Firm F-2 Consolidated Balance Sheets as of October 31, 2024 and 2023 F-3 Consolidated Statements of Operations and Comprehensive Loss for the Years Ended October 31, 2024 and 2023 F-4 Consolidated Statements of Redeemable Convertible Preferred Shares and Shareholdersâ€™ Equity (Deficit) for the Years Ended October 31, 2024 and 2023 F-5 Consolidated Statement of Cash Flows for the Years ended October 31, 2024 and 2023 F-6 Notes to Consolidated Financial Statements F-7 F-1 Â Â REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM Â To the Shareholders and Board of DirectorsenGene Holdings Inc.: Opinion on the Consolidated Financial StatementsWe have audited the accompanying consolidated balance sheets of enGene Holdings Inc. (the â€œCompanyâ€) as of October 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred shares and shareholdersâ€™ equity (deficit), and cash flows for the years then ended, and the related notes (collectively, the â€œconsolidated financial statementsâ€). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of October 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles. Basis for Opinion These consolidated financial statements are the responsibility of the Companyâ€™s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Companyâ€™s internal control over financial reporting. Accordingly, we express no such opinion. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion. Â /s/ KPMG LLP Â We have served as the Companyâ€™s auditor since 2021. Montreal, Canada December 19, 2024 F-2 Â ENGENE HOLDINGS INC. CONSOLIDATED BALANCE SHEETS (AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA) Â Â October 31,2024 Â Â October 31,2023 Â Assets Â Â Â Â Â Â Current assets: Â Â Â Â Â Â Cash and cash equivalents Â $ 173,004 Â Â $ 81,521 Â Marketable securities - short term Â Â 65,328 Â Â Â â€” Â Restricted investments Â Â 72 Â Â Â 76 Â Investment tax credits receivable Â Â 332 Â Â Â 2,343 Â Prepaid and other current assets Â Â 8,626 Â Â Â 1,500 Â Total current assets Â Â 247,362 Â Â Â 85,440 Â Marketable securities - long term Â Â 59,527 Â Â Â â€” Â Property and equipment, net Â Â 1,169 Â Â Â 589 Â Operating lease right of use asset Â Â 1,741 Â Â Â â€” Â Other assets Â Â 1,374 Â Â Â 930 Â Total assets Â $ 311,173 Â Â $ 86,959 Â Liabilities and shareholdersâ€™ equity Â Â Â Â Â Â Current liabilities: Â Â Â Â Â Â Accounts payable Â $ 1,411 Â Â $ 1,156 Â Accrued expenses and other current liabilities Â Â 12,128 Â Â Â 3,539 Â Operating lease liabilities, current Â Â 423 Â Â Â â€” Â Current portion of note payable Â Â 699 Â Â Â 562 Â Total current liabilities Â Â 14,661 Â Â Â 5,257 Â Note payable, net of current portion Â Â 22,473 Â Â Â 9,216 Â Operating lease liabilities, net of current portion Â Â 1,427 Â Â Â â€” Â Total liabilities Â Â 38,561 Â Â Â 14,473 Â Â Â Â Â Â Â Â Shareholdersâ€™ equity: Â Â Â Â Â Â Common shares, noÂ par value; unlimitedÂ shares authorized, 50,976,676Â and 23,197,976Â shares issued and outstanding as of October 31, 2024 and 2023, respectively. Â Â 509,811 Â Â Â 259,373 Â Additional paid-in capital Â Â 18,950 Â Â Â 13,717 Â Accumulated other comprehensive loss Â Â (1,419) Â Â (1,016) Accumulated deficit Â Â (254,730) Â Â (199,588) Total shareholdersâ€™ equity Â Â 272,612 Â Â Â 72,486 Â Total liabilities and shareholdersâ€™ equity Â $ 311,173 Â Â $ 86,959 Â Â The accompanying notes are an integral part of these consolidated financial statements. F-3 Â ENGENE HOLDINGS INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA) Â Â Year Ended October 31, Â Â 2024 Â Â 2023 Â Operating expenses: Â Â Â Â Â Â Research and development Â $ 38,315 Â Â $ 16,458 Â General and administrative Â Â 23,982 Â Â Â 9,602 Â Total operating expenses Â Â 62,297 Â Â Â 26,060 Â Loss from operations Â Â 62,297 Â Â Â 26,060 Â Other (income) expense, net: Â Â Â Â Â Â Change in fair value of convertible debentures embedded derivative liabilities Â Â â€” Â Â Â 21,421 Â Change in fair value of warrant liabilities Â Â â€” Â Â Â (10,849) Change in fair value of convertible debentures Â Â â€” Â Â Â 56,212 Â Interest income Â Â (10,413) Â Â (1,117) Interest expense Â Â 2,798 Â Â Â 4,953 Â Loss on extinguishment of convertible debentures Â Â â€” Â Â Â 3,091 Â Gain on extinguishment of debt Â Â 366 Â Â Â â€” Â Other expense, net Â Â 113 Â Â Â 129 Â Total other (income) expense, net Â Â (7,136) Â Â 73,840 Â Net loss before income taxes Â Â 55,161 Â Â Â 99,900 Â Provision for (recovery of) income taxes Â Â (19) Â Â 17 Â Net loss Â $ 55,142 Â Â $ 99,917 Â Deemed dividend attributable to redeemable convertibleÂ Â Â preferred shareholders Â Â â€” Â Â Â 4,822 Â Net loss attributable to common shareholders, basic andÂ Â Â diluted Â $ 55,142 Â Â $ 104,739 Â Â Â Â Â Â Â Â Other comprehensive loss: Â Â Â Â Â Â Unrealized loss on available-for-sale investments Â Â (403) Â Â â€” Â Total comprehensive loss Â $ 54,739 Â Â $ 99,917 Â Â Â Â Â Â Â Â Net loss per share of common shares, basic and diluted Â $ 1.46 Â Â $ 151.22 Â Weighted-average common shares outstanding, basic and diluted Â Â 37,782,346 Â Â Â 692,609 Â Â The accompanying notes are an integral part of these consolidated financial statements. F-4 Â ENGENE HOLDINGS INC. CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERSâ€™ EQUITY (DEFICIT) (AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA) Â Â Class A Redeemable Convertible Preferred Shares Â Â Class B Redeemable Convertible Preferred Shares Â Â Class C Redeemable Convertible Preferred Shares Â Â Â Common Shares Â Â Additional Paid in Â Â Accumulated Other Comprehensive Â Â Accumulated Â Â Total Shareholdersâ€™Equity Â Â Shares* Â Â Amount Â Â Shares* Â Â Amount Â Â Shares* Â Â Amount Â Â Â Shares* Â Â Amount Â Â Capital Â Â Loss Â Â Deficit Â Â (Deficit) Â Balance at October 31, 2022 Â Â 266,696 Â Â $ 1,899 Â Â Â 156,036 Â Â $ 1,554 Â Â Â 5,560,607 Â Â $ 49,665 Â Â Â Â 665,767 Â Â $ 16,390 Â Â $ 7,683 Â Â $ (1,016) Â $ (99,671) Â $ (76,614) Exercise of stock options Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 47,186 Â Â Â 79 Â Â Â (35) Â Â â€” Â Â Â â€” Â Â Â 44 Â Issuance of common shares upon cashless exercise of options Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 15,494 Â Â Â 11 Â Â Â (11) Â Â â€” Â Â Â â€” Â Â Â â€” Â Conversion and exchange of Old enGene convertible debentures and common share warrants into enGene Holdings common shares and common share warrants in connection with the Reverse Recapitalization Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 6,379,822 Â Â Â 138,410 Â Â Â 1,983 Â Â Â â€” Â Â Â â€” Â Â Â 140,393 Â Conversion and exchange of redeemable convertible preferred shares into common shares in connection with the Reverse Recapitalization Â Â (266,696) Â Â (1,899) Â Â (156,036) Â Â (1,554) Â Â (5,560,607) Â Â (49,665) Â Â Â 5,983,339 Â Â Â 53,118 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 53,118 Â Common shares and common share warrants issued upon Reverse Recapitalization and PIPE Financing, net of issuance costs of $11.1Â million Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 10,106,368 Â Â Â 51,365 Â Â Â 647 Â Â Â â€” Â Â Â â€” Â Â Â 52,012 Â Share-based compensation expense Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â â€” Â Â â€” Â Â Â 3,450 Â Â Â â€” Â Â Â â€” Â Â Â 3,450 Â Net loss Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â (99,917) Â Â (99,917) Balance at October 31, 2023 Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 23,197,976 Â Â $ 259,373.00 Â Â $ 13,717 Â Â $ (1,016) Â $ (199,588) Â $ 72,486 Â Exercise of stock options Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 116,752 Â Â Â 295 Â Â Â (182) Â Â â€” Â Â Â â€” Â Â Â 113 Â Share-based compensation expense Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â â€” Â Â Â â€” Â Â Â 5,324 Â Â Â â€” Â Â Â â€” Â Â Â 5,324 Â Issuance of common shares in connection with February PIPE Financing, net of issuance costs Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 20,000,000 Â Â Â 187,614 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 187,614 Â Issuance of common share in connection with October PIPE Financing, net of issuance costs Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 6,758,311 Â Â Â 56,318 Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â 56,318 Â Issuance of warrants in connection with Amended Term Loan Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â â€” Â Â Â â€” Â Â Â 319 Â Â Â â€” Â Â Â â€” Â Â Â 319 Â Issuance of common shares upon exercise of warrants Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 520,282 Â Â Â 6,114 Â Â Â (131) Â Â â€” Â Â Â â€” Â Â Â 5,983 Â Issuance of common shares upon cashless exercise of warrants Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 383,355 Â Â Â 97 Â Â Â (97) Â Â â€” Â Â Â â€” Â Â Â â€” Â Other comprehensive loss Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â (403) Â Â â€” Â Â Â (403) Net loss Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â (55,142) Â Â (55,142) Balance at October 31, 2024 Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â Â 50,976,676 Â Â $ 509,811 Â Â $ 18,950 Â Â $ (1,419) Â $ (254,730) Â $ 272,612 Â *- The shares have been retrospectively restated to reflect exchange of shares upon the close of Reverse Recapitalization. See Notes 1 and 3. The accompanying notes are an integral part of these consolidated financial statements. F-5 Â ENGENE HOLDINGS INC. CONSOLIDATED STATEMENT OF CASH FLOWS (AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA) Â Â Year ended October 31, Â Â 2024 Â Â 2023 Â Cash flows from operating activities: Â Â Â Â Â Â Net loss Â $ (55,142) Â $ (99,917) Adjustments to reconcile net loss to net cash used in operating activities: Â Â Â Â Â Â Â Â Â Non-cash interest expense Â Â 806 Â Â Â 778 Â Â Â Â Loss on extinguishment of convertible debentures Â Â â€” Â Â Â 3,091 Â Â Â Â Gain on extinguishment of debt Â Â 366 Â Â Â â€” Â Â Â Â Change in fair value of warrant liabilities Â Â â€” Â Â Â (10,849) Â Â Â Change in fair value of convertible debenture embedded derivative liabilities Â Â â€” Â Â Â 21,421 Â Â Â Â Change in fair value of convertible debentures Â Â â€” Â Â Â 56,212 Â Â Â Â Loss on the disposal of property and equipment Â Â 22 Â Â Â â€” Â Â Â Â Debt issuance costs expensed upon issuance of convertible debentures recorded usingÂ Â Â Â the fair value option Â Â â€” Â Â Â 924 Â Â Â Â Non-cash lease expense Â Â 163 Â Â Â â€” Â Â Â Â Amortization of premium/discount on marketable securities Â Â (232) Â Â â€” Â Â Â Â Unrealized foreign currency (gain) losses Â Â (6) Â Â 489 Â Â Â Â Share-based compensation expense Â Â 5,324 Â Â Â 3,450 Â Â Â Â Depreciation of property and equipment Â Â 323 Â Â Â 175 Â Â Â Â Changes in operating assets and liabilities: Â Â Â Â Â Â Â Â Â Â Â Â Investment tax credit receivable Â Â 2,011 Â Â Â (1,007) Â Â Â Â Â Â Prepaid expenses and other assets Â Â (7,566) Â Â (751) Â Â Â Â Â Â Accounts payable Â Â 474 Â Â Â 373 Â Â Â Â Â Â Â Accrued expenses and other liabilities Â Â 5,225 Â Â Â 868 Â Â Â Â Â Â Â Lease liabilities Â Â (49) Â Â â€” Â Â Â Â Â Â Â Â Â Net cash used in operating activities Â Â (48,281) Â Â (24,743) Cash flows from investing activities Â Â Â Â Â Â Purchases of property and equipment Â Â (925) Â Â (318) Purchases of investments Â Â (125,028) Â Â â€” Â Â Â Â Â Â Â Â Â Net cash used in investing activities Â Â (125,953) Â Â (318) Cash flows from financing activities Â Â Â Â Â Â Proceeds from PIPE financings Â Â 260,149 Â Â Â 56,892 Â Payments of issuance costs associated with the 2024 PIPE Financings Â Â (12,386) Â Â â€” Â Proceeds from FEAC trust account in connection with Reverse Recapitalization Â Â â€” Â Â Â 7,363 Â Payment of Reverse Recapitalization and PIPE Financing costs Â Â (613) Â Â (10,497) Proceeds from issuance of April 2023 Notes Â Â â€” Â Â Â 38,000 Â Payment of issuance costs associated with April 2023 Notes Â Â â€” Â Â Â (924) Repayment of convertible debentures Â Â â€” Â Â Â (3,176) Proceeds from exercise of stock options Â Â 113 Â Â Â 44 Â Proceeds from exercise of common share warrants Â Â 5,983 Â Â Â â€” Â Repayments of term loan principal Â Â (9,445) Â Â (1,555) Proceeds from issuance of term loan Â Â 22,500 Â Â Â â€” Â Payments of debt issuance costs associated with the term loan Â Â (585) Â Â â€” Â Â Â Â Â Â Â Â Â Net cash provided by financing activities Â Â 265,716 Â Â Â 86,147 Â Effect of exchange rate changes on cash Â Â 1 Â Â Â 1 Â Net increase in cash and cash equivalents Â Â 91,483 Â Â Â 61,087 Â Cash and cash equivalents at beginning of period Â Â 81,521 Â Â Â 20,434 Â Cash and cash equivalents at end of period Â $ 173,004 Â Â $ 81,521 Â Supplemental cash flow information: Â Â Â Â Â Â Cash paid for interest Â $ 1,925 Â Â $ 1,398 Â Supplemental disclosure of non-cash investing and financing activities Â Â Â Â Â Â Reverse Recapitalization and PIPE financing transaction costs included within accruedÂ Â Â expenses Â $ 3,831 Â Â $ 613 Â Conversion of Preferred Shares upon Reverse Recapitalization Â Â â€” Â Â Â 53,118 Â Warrant value issued as part of Amended Term Loan Â Â 319 Â Â Â â€” Â Conversion of Convertible Debentures upon Reverse Recapitalization Â Â â€” Â Â Â 113,627 Â Reclassification of warrant liability to equity upon Reverse Recapitalization Â Â â€” Â Â Â 1,983 Â Liabilities assumed upon Reverse Recapitalization Â Â â€” Â Â Â 1,130 Â Warrant liability recognized upon issuance of term loan Â Â â€” Â Â Â 1,420 Â Settlement of derivative liability upon repayment and conversion of convertible debentures Â Â â€” Â Â Â 25,217 Â Right of use assets obtained in exchange for lease liabilities Â Â 1,904 Â Â Â â€” Â Fixed assets included in accrued expenses and accounts payable Â Â â€” Â Â Â 58 Â Settlement of April 2023 Notes through the issuance of May 2023 Notes and warrants Â Â â€” Â Â Â 8,000 Â Â The accompanying notes are an integral part of these consolidated financial statements. F-6 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â 1. Description of BusinessenGene Holdings Inc. (together with its consolidated subsidiaries â€œenGeneâ€ or the â€œCompanyâ€) formed in connection with the Merger Agreement (as defined below) was incorporated as 14963148 Canada Inc. under the federal laws of Canada on April 24, 2023 and changed its name to enGene Holdings Inc. on May 9, 2023. On October 31, 2023, enGene Holdings Inc. continued from being a corporation incorporated under and governed by the Canada Business Corporations Act to a company continued to and governed by the Business Corporations Act (British Columbia). The Company is a clinical-stage biotechnology company focused on developing genetic medicines to improve the lives of patients, and its head office is located in Montreal, Quebec, Canada. The Company is developing non-viral genetic medicines based on its novel and proprietary dually derived chitosan, or â€œDDXâ€, gene delivery platform, which allows localized delivery of multiple gene cargos directly to mucosal tissues and other organs.Merger with Forbion European Acquisition Corp.Forbion European Acquisition Corporation (â€œFEACâ€) was a special purpose acquisition company (â€œSPACâ€), incorporated as a Cayman Island exempted company on August 9, 2021 and formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more business or entities. On October 31, 2023 (the â€œClosing Dateâ€), the Company, FEAC, and enGene Inc., consummated the merger (the â€œReverse Recapitalizationâ€) pursuant to a business combination agreement, dated as of May 16, 2023 (the â€œMerger Agreementâ€). The transaction was accounted for as a â€œreverse recapitalizationâ€ in accordance with accounting principles generally accepted in the United States (â€œU.S. GAAPâ€). Under this method of accounting, FEAC was treated as the â€œacquiredâ€ company for financial reporting purposes. This determination is primarily based on the fact that subsequent to the Reverse Recapitalization, senior management of Old enGene continued as senior management of the combined company; Old enGene identified a majority of the members of the board of directors of the combined company; the name of the combined company is enGene Holdings Inc. and it utilized Old enGeneâ€™s current headquarters, and Old enGeneâ€™s operations comprise the ongoing operations of the combined company. Accordingly, for accounting purposes, the Company is considered to be a continuation of Old enGene, with the net identifiable assets of FEAC deemed to have been acquired by Old enGene in exchange for Old enGene common shares accompanied by a recapitalization, with no goodwill or intangible assets recorded. The number of redeemable convertible preferred shares, number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization, have been retrospectively restated to reflect an exchange ratio of approximately 0.18048 (the â€œExchange Ratioâ€) established in the Merger Agreement. Operations prior to the Reverse Recapitalization are those of Old enGene.As a result of the Reverse Recapitalization, the Company became a publicly traded company, and listed its Common Shares and warrants on the Nasdaq Global Market under the symbols â€œENGNâ€ and â€œENGNW,â€ respectively, commencing trading on November 1, 2023, with Old enGene, a subsidiary of the Company, continuing the existing business operations.Liquidity and Going Concern In accordance with Accounting Standards Codification (â€œASCâ€) 205-40, Going Concern, the Company has evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about the Companyâ€™s ability to continue as a going concern within one year after the date these consolidated financial statements are issued.The Companyâ€™s consolidated financial statements have been prepared assuming the Company will continue as a going concern, which presumes the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the ordinary course of business.As an emerging growth entity, the Company has devoted substantially all of its resources since inception to organizing and staffing the Company, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, research and development activities for developing non-viral genetic medicines and other compounds, establishing arrangements with third parties for the manufacture of its product candidates and component materials, and providing general and administrative support for these operations. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future. The Company has not yet commercialized any product candidates and does not expect to generate revenue from sales of any product candidates or from other sources for several F-7 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â years, if at all. The Company will need substantial additional funding to support its continuing operations and pursue its development strategy.The Company has incurred a net loss of $55.1 million and negative cash flows from operating activities of $48.3 million for year ended October 31, 2024, and, as of that date, has an accumulated deficit of $254.7 million. To date, the Company has not generated any revenues and has financed its liquidity needs primarily through the 2024 PIPE Financings, the Reverse Recapitalization and the PIPE financing conducted by the Company as part of the Reverse Recapitalization (the â€œPIPE Financingâ€), debt and convertible debentures, and issuance of redeemable convertible preferred shares and warrants.The Companyâ€™s ability to continue as a going concern depends on its ability to successfully develop and commercialize its products, achieve and maintain profitable operations, as well as the adherence to conditions of outstanding loans. As of the issuance date of these consolidated financial statements, the Company expects that its existing cash and cash equivalents as of October 31, 2024 will be sufficient to fund its operating expenses and debt obligations requirements for at least the next 12 months from the issuance date of these consolidated financial statements. Effective from the Companyâ€™s first quarter interim condensed consolidated financial statements, the Company has ceased its disclosure of the existence of a material uncertainty that raised substantial doubt about the Companyâ€™s ability to continue as a going concern due to the February 2024 PIPE Financing. 2. Summary of Significant Accounting PoliciesBasis of PresentationThe accompanying consolidated financial statements are prepared in accordance with U.S. GAAP and include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (â€œASCâ€) and as amended by Accounting Standards Updates (â€œASUâ€™sâ€) of the Financial Accounting Standards Board (â€œFASBâ€).The consolidated financial statements are expressed in US dollars. The consolidated financial statements have been prepared on a historical cost basis, except for items that are required to be accounted for at fair value.As the merger with FEAC has been accounted for as a reverse recapitalization, the historical operations of the Company represent that of Old enGene which is the accounting predecessor. The number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization have been retrospectively restated to reflect the Exchange Ratio of approximately 0.18048 established in the Merger Agreement. Please see Note 3, Reverse Recapitalization for additional information.Use of EstimatesThe preparation of the Companyâ€™s consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include but are not limited to the accrual of research and development expenses, share-based payments and the recoverability of investment tax credits receivable and, in addition, for fiscal 2023: the valuations of common shares, redeemable convertible preferred shares, warrants to purchase redeemable convertible preferred shares, convertible debentures, and embedded derivatives on convertible debt. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Actual results could differ from those estimates and such differences may be material to the consolidated financial statements.Segment InformationOperating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates as a single business segment focused on research, discovery, and clinical development of human genetic medicine products. The majority of the Companyâ€™s tangible assets are held in Canada. F-8 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Risk of Concentrations of Credit and Off-Balance Sheet RiskFinancial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits. Management believes that the Company is not currently exposed to significant credit risk as the Companyâ€™s deposits were held in custody at third-party financial institutions.The Company's investment policy limits investments to certain types of securities issued by the U.S. Government and its agencies, as well as institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of marketable securities to the extent recorded on the Consolidated Balance Sheets. As of October 31, 2024 and 2023, the Company had no off-balance sheet concentrations of credit risk.The Company is dependent on third-party CDMOs and CRO with whom it does business. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities in its programs. The Company also relies on a limited number of third-party CROs to perform research and development activities on its behalf. These programs could be adversely affected by significant interruption from these providers.Cash and Cash EquivalentsThe Company considers all short-term, highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. The Companyâ€™s cash and cash equivalents include bank balances, demand deposits and other short-term, highly liquid investments. The fair value of cash and cash equivalents approximate the amortized cost. The Company had $173.0 million of cash and cash equivalents as of October 31, 2024 and $81.5 million of cash as of October 31, 2023.Marketable securitiesThe Company's marketable securities are maintained by investment managers and consist of money market funds, U.S. government agency securities and treasuries. If the remaining contractual maturity is within one year from the balance sheet date, the marketable securities are classified as current and otherwise, they are classified as non-current assets.Investment in marketable securities is classified as available-for-sale and is reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale securities are reported as a separate component of stockholders' equity in other comprehensive loss. Premium or discounts from par value are amortized to investment income over the life of the underlying investment.The Company periodically evaluates the need for an allowance for credit losses. The evaluation includes consideration of several qualitative and quantitative factors, including whether it has plans to sell the security, whether it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis, and if the entity has the ability and intent to hold the security to maturity, and the portion of any unrealized loss that is the result of a credit loss. Factors considered in making these evaluations include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, expected cash flows from securities, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and the Company's strategy and intentions for holding the marketable security.When the fair value is below the amortized cost of the asset, an estimate of expected credit losses is made. The Company records credit losses in the consolidated statements of operations and comprehensive loss as a credit loss expense within other income, net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale securities.Accrued interest receivable related to the Company's available-for-sale securities is presented within prepaids and other current assets on the Company's consolidated balance sheets. The Company has elected the practical expedient available to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivable associated with its marketable securities. F-9 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Property and EquipmentProperty and equipment are comprised mainly of research and development equipment, computer hardware and software, office furniture and equipment, and leasehold improvements. Property and equipment are stated at cost less accumulated depreciation and accumulated impairment losses, if applicable. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:Â Â Â Estimated Useful Life Lab equipment Â 5 years Computer equipment Â 3 years Computer software Â 5 years Office furniture Â 5 years Leasehold improvements Â Shorter of remaining lease term or useful life Â Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheet and any resulting gains or losses are included in the consolidated statements of operations and comprehensive loss in the period of disposal.The Company reviews long-lived assets, such as property and equipment, for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. If indicators of impairment are present, the assets are tested for recoverability by comparing the carrying amount of the assets to the related estimated future undiscounted cash flows that the assets are expected to generate. If the expected undiscounted cash flows are less than the carrying value of the assets, then the assets are considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows. To date, no such impairment losses have been recorded.LeasesThe Company adopted FASB ASC 842 with an effective date of November 1, 2019, using the modified retrospective transition approach which uses the effective date as the date of initial application. In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use (â€œROUâ€) asset and a lease liability on the consolidated balance sheet for all leases with an initial lease term of greater than 12 months. The Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet.The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.Lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Companyâ€™s lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. F-10 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Fair Value Measurements of Financial InstrumentsCertain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:oLevel 1â€”Quoted prices in active markets for identical assets or liabilities.oLevel 2â€”Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.oLevel 3â€”Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrumentâ€™s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At October 31, 2024, financial instruments measured at fair value on a recurring basis include marketable securities (see Note 5, Marketable Securities, and Note 4, Fair Value Measurements). The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term nature.Fair Value OptionThe Company elected the fair value option of accounting of ASC 825 for all convertible debentures issued in fiscal 2023 from their issuance date in order to not have to bifurcate any embedded derivatives in accordance with ASC 815. The notes for which the fair value option of accounting is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the notes accounted for at fair value, which include accrued interest, if any, are recorded as a component of other expense (income), net in the consolidated statement of operations and comprehensive loss. The Company has not elected to present interest expense separately from changes in fair value and therefore will not present interest expense associated with the notes. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income. During the year ended October 31, 2023, the Company did not record any changes in fair value related to instrument-specific credit risk. All costs associated with the issuance of the convertible debentures accounted for using the fair value option were expensed upon issuance.Debt Issuance CostsThe Company capitalizes certain legal, accounting, and other third-party fees that are directly associated with the issuance of debt not accounted for using the fair value option as debt issuance costs. Debt issuance costs are recorded as a direct reduction of the carrying amount of the associated debt on the Companyâ€™s consolidated balance sheets and amortized as interest expense on the Companyâ€™s consolidated statements of operations and comprehensive loss using the effective interest method.Convertible Debenture Embedded Derivative LiabilitiesThe Companyâ€™s convertible debentures contained certain features that meet the definition of embedded derivatives requiring bifurcation from the convertible debenture instrument, for which the fair value option was not elected, as a separate compound derivative. The convertible debenture embedded derivative liabilities are initially measured at fair value on issuance and is subject to remeasurement at each reporting period with changes in fair value recognized in the change in fair value of derivative liabilities, net in the consolidated statements of operations and comprehensive loss. Â F-11 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Common Share and Preferred Share WarrantsThe Company accounts for its common share warrants and redeemable convertible preferred shares warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants that have been determined to be classified as liabilities are recorded on the consolidated balance sheets at their fair value on the date of issuance and remeasured to fair value at each reporting period, with the changes in fair value recognized in the change in fair value of warrant liabilities, net in the consolidated statements of operations and comprehensive loss. The Company adjusted the liability for changes in the fair value of these warrants until the earlier of the exercise of the warrants, the expiration of the warrants, or until such time as the warrants were no longer considered liability.Convertible DebenturesThe Companyâ€™s 2022 Notes (as defined in Note 9, Notes Payable) are convertible debentures that consist of a debt instrument, a minimum interest obligation, and a share conversion feature. Certain of the convertible debentures issued by the Company also included warrants to purchase redeemable convertible preferred shares, which were classified as liabilities. The Company identified embedded derivatives related to certain share conversion and repayment features within the convertible notes that required bifurcation as a single compound derivative instrument. At inception, the Company utilized the residual method to determine the value of the debt instrument based on the difference between gross proceeds and the estimated fair value of the embedded derivative and any warrants that were issued. The debt instrument is accounted for using the amortized cost method. The discounts on debt resulting from any issuance costs, embedded derivatives and warrants are amortized over the life of the debt using the effective interest method. The issuance costs allocated to the embedded derivatives and warrants are expensed at inception.Research and Development ExpensesResearch and development expenses are comprised primarily of costs incurred for our drug discovery efforts and development of our product candidates. These expenses include salaries, employee benefits, and share-based compensation expense for our research and development personnel, materials, supplies, depreciation on and maintenance of research equipment, the cost of services provided by outside CROs and consultants to conduct research and development activities including costs of clinical trials and manufacturing, and the allocable portions of facility costs, such as rent, utilities, and general support services. All costs associated with research and development are expensed as incurred.Management estimates the Companyâ€™s accrued research and development expenses as of each balance sheet date in the Companyâ€™s financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.Patent CostsAll patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent-related costs are classified as general and administrative expenses within the Companyâ€™s consolidated statements of operations. F-12 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Share-Based CompensationThe Company has an incentive equity plan (the â€œ2023 Incentive Equity Planâ€ or the â€œ2023 Planâ€), whereby employees render services as consideration for equity instruments. The 2023 Plan was adopted on October 31, 2023 upon the completion of the Reverse Recapitalization and superseded Old enGeneâ€™s employee stock option plan (the â€œESOPâ€) and equity incentive plan (the â€œEIPâ€) (collectively, the â€œOld Plansâ€). The Company measures all share-based awards granted to employees, officers, directors and non-employees based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures of its share-based awards as they occur. The Company issues share-based awards with service-based vesting conditions and awards with both performance and service-based vesting conditions. For share-based awards with service-based vesting conditions, the Company records the expense using the straight-line method including when such awards have graded vesting. For share-based awards with both performance and service-based vesting conditions, the Company records the expense using an accelerated attribution method, once the performance conditions are considered probable of being achieved, using managementâ€™s best estimate.The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the Companyâ€™s common shares, expected share price volatility, the expected term of the award, the risk-free interest rate for a period that approximates the expected term of the option, and the Companyâ€™s expected dividend yield. The Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies with similar characteristics including market capitalization, stage of development, therapeutic focus and certain financial measures. The expected volatility has been determined using an average of the historical volatility measures of this group of guideline companies. The expected option term was calculated based on the simplified method for awards with only service based vesting conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to develop an estimate based on participant behavior. For awards with both performance and service based vesting conditions, the expected term has been determined using managementâ€™s best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, if any, and comparison to expected terms used by peers. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common shares; therefore, the expected dividend yield is assumed to be zero.Prior to the consummation of the Reverse Recapitalization, because there was no public market for the Companyâ€™s common shares, the Board of Directors has determined the fair value of the Companyâ€™s common shares based on third-party valuations of the Companyâ€™s common shares. Initially, the estimated enterprise equity value of the Company was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Companyâ€™s various securities of its capital structure using an option pricing method, or OPM, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another.Significant assumptions used in the OPM to determine the fair value of common shares include volatility, discount for lack of marketability, and the expected timing of a future liquidity event such as an initial public offering (â€œIPOâ€), or sale of the Company in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios. In addition, the Companyâ€™s Board of Directors considered various objective and subjective factors to determine the fair value of the Companyâ€™s common shares as of each grant date, including the prices at which Old enGene sold shares of redeemable convertible preferred shares and the superior rights and preferences of the redeemable convertible preferred shares relative to its common shares at the time of each grant, external market conditions, the progress of the Companyâ€™s research and development programs, the Companyâ€™s financial position, including cash on hand, and its historical and forecasted performance and operating results, and the lack of an active public market for the Companyâ€™s common shares and redeemable convertible preferred shares, among other factors.The assumptions underlying these valuations represented managementâ€™s best estimate, which involved inherent uncertainties and the application of managementâ€™s judgment and these valuations are sensitive to changes in the unobservable inputs. As a result, if the Company had used different assumptions or estimates or if there are changes to the unobservable inputs, the fair value of its common shares and share-based compensation expense could have been materially different.Subsequent to becoming a publicly traded Company upon the consummation of the Reverse Recapitalization, the fair value of common shares underlying equity awards is based on the market price of the Companyâ€™s common stock at the date of the grant. F-13 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â The Companyâ€™s share-based compensation expense is recorded in general and administrative and research and development expenses in the Companyâ€™s consolidated statements of operations and comprehensive loss.Income TaxesThe Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Companyâ€™s consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on differences between the consolidated financial statement carrying amounts and the tax basis of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.Comprehensive LossComprehensive loss includes net loss as well as other changes in shareholdersâ€™ deficit that result from transactions and economic events other than those with shareholders. The Companyâ€™s comprehensive loss includes foreign currency translation.Net Loss Per ShareBasic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common shares. Net loss per share attributable to common shareholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Companyâ€™s common shares and participating securities. Net loss attributable to common shareholders is allocated first based on dividend rights and then to common and preferred shareholders based on ownership interests on an as-converted basis as if all the earnings for the period had been distributed.When considering the impact of the convertible equity instruments, diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred shareholders and warrant holders based on dividend rights and then to common and preferred shareholders and warrant holders based on ownership interests. As preferred shares have converted to common shares at the completion of Reverse Recapitalization, the abovementioned policy is only applicable for the year ended October 31, 2023. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, and the potential issuance of common shares upon the conversion of the convertible notes. Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders is generally the same as basic net loss per share attributable to common shareholders because dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. See Note 15, Net Loss per Share, for further detail.Deferred Transaction Costs The Company capitalized certain legal, professional accounting and other third-party fees that were directly associated with the Reverse Recapitalization and PIPE Financing as deferred transaction costs until such transaction was consummated. After the consummation of such transaction, these costs were recorded within equity as a reduction of the common share and warrants value within additional paid in capital, for both instruments issued and assumed to shareholders of FEAC and to PIPE financing investors, were allocated to each on a relative fair value basis. The Company incurred a total of $11.3 million of transaction costs as part of the Reverse Recapitalization and PIPE Financing. In addition, transaction costs of $0.8 million related to the issuance of the April 2023 Notes and the May 2023 Notes for which the fair value option of accounting was elected and those allocated to the liability classified F-14 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â warrants issued as part of the 2023 Financing are not deferred and are included in general and administrative expenses in the Companyâ€™s consolidated statements of operations and comprehensive loss.Government Assistance Programs for Research and Development ExpendituresThe Company was eligible to claim Canadian federal and provincial tax credits as a Canadian controlled private corporation (â€œCCPCâ€) on eligible scientific research and experimental development (â€œSR&EDâ€) expenditures through September 2023, at which time the Company lost its status as a CCPC. In addition, effective for fiscal 2023, the Companyâ€™s maximum refundable tax credits were reduced due to the Companyâ€™s taxable capital, as defined in the Income Tax Act (Canada), which reduction in credits has been recorded in the fourth quarter. The Canadian federal government offers a tax incentive to companies performing research and development activities in Canada and this tax incentive can be refunded or used to reduce federal income taxes in Canada otherwise payable. Such credits, if not refunded or used in the year earned, can be carried forward for a period of twenty years. The Quebec provincial government offers a similar refundable incentive. The investment tax credits recorded are based on managementâ€™s estimates of amounts expected to be recovered and are subject to audit by the taxation authorities, the resulting adjustments of which could be significant. Following the loss of CCPC status, the Companyâ€™s SR&ED tax credits will be earned at a lower rate and some will no longer be refundable. Amounts received or receivable resulting from government assistance programs, including investment tax credits for SR&ED, are recognized when there is reasonable assurance that the amount will be received, and all attached conditions will be complied with. Reimbursements of eligible SR&ED expenditures pursuant to government assistance programs are received in cash. The amounts receivable are recorded as reductions of research and development costs when the related costs have been incurred and there is reasonable assurance regarding collection of the claim. During the years ended October 31, 2024 and 2023, the Company recorded $0.4 million and $1.1 million, respectively, as a reduction of research and development expense associated with SR&ED investment tax credits. Recently Adopted Accounting Pronouncements In June 2016, the FASB issued ASU No. 2016-13, Financial Instrumentsâ€”Credit Losses (Topic 326)â€”Measurement of Credit Losses on Financial Instruments (â€œASU 2016-13â€). This new standard changes the impairment model for most financial assets and certain other instruments. Entities will be required to use a model that will result in the earlier recognition of allowances for losses for trade and other receivables, held-to-maturity debt securities, loans, and other instruments. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. In November 2019, the FASB issued ASU 2019-10, Financial Instruments â€“ Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) (â€œASC 2019-10â€), which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, for entities meeting the definition of a smaller reporting company. The Company adopted ASU 2016-13 effective November 1, 2023 and the adoption did not have a material impact on the consolidated financial statements.Recently Issued Accounting Pronouncements â€“ Not Yet Adopted In June 2022, the FASB issued ASU No. 2022-03, Fair Value Measurement (Topic 820) â€“ Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions, which amends guidance in ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company does not expect that the adoption of this standard will have a material impact on its financial statements and related disclosures.In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280) â€“ Improvements to Reportable Segment Disclosures, which requires incremental disclosure of segment information on an interim and annual basis. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application to all prior periods presented in the financial statements is required for public entities. The Company is currently evaluating the impact of the guidance on the financial statements disclosures.In November 2024, the FASB issued ASU 2024-03, Income Statementâ€”Reporting Comprehensive Incomeâ€”Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires entities to disclose additional information about specific expense categories in the notes to the financial statements. The ASU is effective for annual periods beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is F-15 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the effect of this update on its consolidated financial statements and related disclosures. 3. Reverse RecapitalizationOn October 31, 2023 (the â€œClosing Dateâ€), FEAC, Old enGene, and the Company consummated the merger pursuant to the Merger Agreement, dated as of May 16, 2023. As a result of the Reverse Recapitalization, the Company became a publicly traded company, with old enGene, a subsidiary of the Company, continuing the existing business operations. At the effective time of the Reverse Recapitalization: â€¢each outstanding share of Old enGene common stock was exchanged for the Companyâ€™s common shares at the Exchange Ratio;â€¢each share of Old enGeneâ€™s redeemable convertible preferred shares outstanding immediately prior to the close of the Reverse Recapitalization was exchanged for shares of the Companyâ€™s common shares based on the same Exchange Ratio, with no dividends or distributions being declared or paid on Old enGeneâ€™s redeemable convertible preferred shares;â€¢the 2022 Notes and May 2023 Notes (each as defined in Note 9, Notes Payable) of Old enGeneâ€™s existing convertible notes outstanding immediately prior to the close of the Reverse Recapitalization were converted to Old enGene common shares at the conversion ratio in place at the time of conversion and were exchanged for shares of the Company at the Exchange Ratio; andâ€¢each outstanding option to purchase Old enGene common stock became fully vested and converted into an option to purchase a number of the Companyâ€™s common shares equal to the number of shares of old enGene common stock subject to such option multiplied by the Exchange Ratio, rounded down to the nearest whole share, at an exercise price per share equal to the current exercise price per share for such option divided by the Exchange Ratio, rounded up to the nearest whole cent;â€¢all of Old enGeneâ€™s outstanding warrants exercisable for common shares in Old enGene were exchanged for warrants exercisable for the Companyâ€™s common shares using the Exchange Ratio, with the warrants maintaining the same terms and conditions;â€¢all of Old enGeneâ€™s existing outstanding Class C warrants outstanding at the time of the Reverse Recapitalization were terminated; andâ€¢all outstanding FEAC Shares of 3,670,927 held by FEAC Sponsor and shareholders were converted into the same number of the Companyâ€™s common shares, and outstanding FEAC warrants of 5,029,444 held by FEAC warrant holders were converted into the same number of warrants to purchase one share of the Companyâ€™s common shares. Upon the close of the Reverse Recapitalization, 13,091,608 common shares of the Company were issued to the Old enGeneâ€™s equity and convertible note holders, 2,679,432 common share warrants of the Company were issued to Old enGeneâ€™s warrant holders, and 2,706,941 common share options of the Company were issued to Old enGeneâ€™s share option holders. In connection with the Merger Agreement, FEAC, the Company, and PIPE Investors entered into Subscription Agreements pursuant to which, the PIPE Investors have agreed to purchase the Companyâ€™s shares and warrants for an aggregate commitment amount of $56.9 million. As part of the PIPE Financing, the Company issued 6,435,441 shares of the Companyâ€™s common shares and 2,702,791 warrants to purchase the Companyâ€™s common shares for an aggregate purchase price equal to $56.9 million on October 31, 2023. The common shares and warrants issued as part of the PIPE Financing were determined to be equity classified. The proceeds were allocated between the common shares and warrants on a relative fair value basis, taking into consideration the quoted market price of the FEAC common shares and warrants on the close of the market on October 31, 2023, resulting in $56.1 million being allocated to the common shares and $0.8 million being allocated to the warrants. In connection with the Merger Agreement, FEAC, the FEAC Sponsor, Forbion Growth Opportunities Fund I Cooperatief U.A. and the other holders of FEAC Class B Shares, Old enGene, the Company and the other parties named therein entered into the Side Letter Agreements, pursuant to which the FEAC Sponsor agreed to surrender and in effect issue to PIPE Investors FEAC Class B shares and FEAC private placement warrants, immediately prior to the closing of the Reverse Recapitalization. Immediately following the Reverse Recapitalization and the PIPE Financing, the Company had 23,197,976 common shares and 10,411,641 warrants outstanding. F-16 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â On October 31, 2023, as part of the close of Reverse Recapitalization, the Company received proceeds of $7.4 million, from the FEAC trust account, net of the redemption payment to FEACâ€™s public shareholders and cash paid from the trust for FEAC expenses. Additionally, the Company received proceeds of approximately $56.9 million from the PIPE Financing. Upon the closing of the Reverse Recapitalization and PIPE Financing, the Company incurred $6.0 million in transaction costs, which was withheld from the proceeds received. The Company incurred a total of $11.1 million of transaction costs associated with the Reverse Recapitalization and PIPE Financing, of which $5.1 million was previously deferred by the Company and netted against the proceeds upon close. The transaction costs were allocated to the common shares and warrants on a relative fair value basis and netted against the proceeds upon close.The following table summarizes the elements of the net proceeds from the Reverse Recapitalization and PIPE Financing transaction as of October 31, 2023:Â Â Recapitalization Â Cash â€“ FEACâ€™s Trust Account and Cash (net of redemptionsÂ Â Â and cash paid for FEAC expenses prior to close) Â $ 7,363 Â Cash â€“ PIPE Financing Â Â 56,892 Â Less transaction costs withheld from cash proceeds on ClosingÂ Â Â Date Â Â (6,024) Cash proceeds received from the Reverse Recapitalization andÂ Â Â PIPE Financing on Closing Date Â $ 58,231 Â Less transaction costs previously deferred and netted againstÂ Â Â proceeds Â Â (5,086) Net cash proceeds from the Reverse Recapitalization and PIPEÂ Â Â Financing Â Â 53,145 Â Â The total transaction costs of $11.1 million were related to third-party legal, accounting services and other professional services to consummate the Reverse Recapitalization and the PIPE Financing incurred by Old enGene. These transaction costs are allocated between common shares and additional paid-in capital, based on the relative fair value of the common shares and warrants issued upon the close of the Reverse Recapitalization, on the Companyâ€™s consolidated balance sheet as the Companyâ€™s common shares have no par value.The following table summarizes the number of common shares outstanding immediately following the consummation of the Reverse Recapitalization and PIPE Financing transaction:Â Â Number of Shares Â Old enGene Shareholders (Excluding Convertible Notes) Â Â 6,711,786 Â FEAC Shareholders, including sponsor's and shareholder withÂ Â Â non-redemption agreement Â Â 3,670,927 Â Convertible Notes - Common Shares Issued Â Â 6,379,822 Â Common shares issued to PIPE Investors Â Â 6,435,441 Â Total common shares outstanding immediately after theÂ Â Â Reverse Recapitalization and PIPE Financing Â Â 23,197,976 Â Â 4. Fair Value MeasurementsThe Company did not have any financial assets or liabilities that required fair value measurement on a recurring basis as of October 31, 2023.The following table presents the Company's fair value hierarchy for financial assets measured at fair value as of October 31, 2024: F-17 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Â Â Â Â Â October 31, 2024 Â Description Â Total Â Â Quoted Prices inActive Marketsfor IdenticalAssets (Level 1) Â Â Significant OtherObservableInputs (Level 2) Â Â Significant OtherObservableInputs (Level 3) Â Assets Â Â Â Â Â Â Â Â Â Â Â Â Cash equivalents Â Â Â Â Â Â Â Â Â Â Â Â Money market funds Â Â 121 Â Â Â 121 Â Â Â â€” Â Â Â â€” Â U.S. government treasuries Â Â 94,236 Â Â Â 94,236 Â Â Â â€” Â Â Â â€” Â Government agency securities Â Â 9,955 Â Â Â â€” Â Â Â 9,955 Â Â Â â€” Â Short term marketable securities: Â Â Â Â Â Â Â Â Â Â Â Â U.S. government treasuries Â Â 51,574 Â Â Â 51,574 Â Â Â â€” Â Â Â â€” Â Government agency securities Â Â 13,754 Â Â Â â€” Â Â Â 13,754 Â Â Â â€” Â Long term marketable securities: Â Â Â Â Â Â Â Â Â Â Â Â U.S. government treasuries Â Â 49,627 Â Â Â 49,627 Â Â Â â€” Â Â Â â€” Â Government agency securities Â Â 9,900 Â Â Â â€” Â Â Â 9,900 Â Â Â â€” Â Total financial assets Â $ 229,167 Â Â $ 195,558 Â Â $ 33,609 Â Â $ â€” Â Â As of October 31, 2024, the Company classified its government agency marketable securities as Level 2 within the valuation hierarchy. The Company estimates the fair value of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly to estimate fair value. These inputs include market pricing based on real time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs.During the years ended October 31, 2024 and 2023, there were no transfers or reclassifications between fair value measure levels of assets or liabilities. The carrying values of all other financial current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.Convertible Debentures Embedded Derivative Liabilities Prior to the Reverse Recapitalization, the Companyâ€™s convertible debentures contained equity conversion options, and certain repayment features, that have been identified as a single compound embedded derivative requiring bifurcation from the host contract for the convertible debentures for which the fair value has not been elected. The Company estimated the fair value of the convertible debenture embedded derivative liabilities on issuance using a probability weighted scenario expected return model. The estimated probability and timing of underlying events triggering the conversion and liquidity repayment features and probability of exercise of the extension features within the convertible debentures as well as discount rates, volatility and share prices are inputs used to determine the estimated fair value of the embedded derivative. The assumptions ranges that the Company used to determine the fair value of the convertible debentures embedded derivative liabilities for the 2022 Notes and BDC Notes that were outstanding as of each respective period (refer to Note 9, Notes Payable) were as follows:Â Â Immediately prior to settlement on Â Â Â October 31, 2023 Â Probability of qualified financing* Â Â 100 % Volatility** Â n/a Â Class C Preferred Share price (CAD)** Â n/a Â Liquidity price at conversion of listing event*** Â $ 8.84 Â Fair value of common share at conversion of listingÂ Â Â event*** Â $ 21.70 Â Discount rate**** Â Â 18.4 % Expected time to respective scenarios Â 0.0Â years Â Â F-18 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â * The probability represents the cumulated probabilities of conversion at various dates before maturity. The probability includes the probability of a SPAC transaction (which corresponds to a listing event for the 2022 Notes and to a liquidity event for the BDC Notes).** Volatility and Class C Preferred share price is not applicable and expected time to scenario is 0.0 years as of October 31, 2023 as the 2022 Notes converted to shares upon the Reverse Recapitalization and the BDC Notes were repaid in full.*** The liquidity price at the conversion of a listing event represents the conversion price of the 2022 Notes upon the merger with FEAC, and the fair value per common share at conversion of a listing event represents the quoted market price of the FEAC common shares on the close of the market on October 31, 2023, immediately prior to the settlement upon the completion of the Reverse Recapitalization.**** Discount rate includes credit risk, discount for lack of marketability and other factors considered in the model.Upon the close of the Reverse Recapitalization the 2022 Notes were converted and exchanged for common shares of the Company, resulting in an extinguishment of the 2022 Notes and related embedded derivative liability. Further the BDC Note (as defined below) was repaid in full. See Note 3, Reverse Recapitalization and Note 10, Convertible Debentures for additional detail. Immediately prior to the conversion and exchange of the 2022 Notes as part of the Reverse Recapitalization, the embedded derivative was measured to a fair value of $24.8 million. Further immediately prior to the repayment of the BDC Note, the embedded derivative liability was measured to a fair value of $0.4 million.The following table provides a summary of the change in the estimated fair value of the Companyâ€™s convertible debentures embedded derivative liabilities for the year ended October 31, 2023:Â Â Total Â Balance as of October 31, 2022 Â Â 3,791 Â Change in fair value of convertible debenture embeddedÂ Â Â derivative liabilities Â Â 21,421 Â Foreign exchange rate translation adjustment Â Â 5 Â Settlement of derivative liability in accordance withÂ Â Â repayment and conversion of convertible debenturesÂ Â Â upon the consummation of the Reverse Recapitalization Â Â (25,217) Balance as of October 31, 2023 Â $ â€” Â Â April 2023 NotesThe Company elected the fair value option of accounting for the April 2023 Notes. The Company recorded the April 2023 Notes at fair value upon the date of issuance, which was determined to be the total cash proceeds received of $8.0 million and was considered a Level 3 measurement within the fair value hierarchy. The April 2023 Notes were repaid through the issuance of $8.0 million in aggregate amount of convertible notes and warrants issued as part of the 2023 Financing. No change in fair value was recorded on the April 2023 Notes during the year ended October 31, 2023, given the close proximity between the issuance date of the notes and the repayment date. As of October 31, 2024 and 2023, the April 2023 Notes are no longer outstanding. May 2023 NotesThe Company elected the fair value option of accounting for the May 2023 Notes. At issuance and for periods prior to the settlement of the May 2023 Notes, the Company estimated the fair value of the May 2023 Notes using a probability weighted scenario expected return model and was considered a Level 3 measurement per the fair value hierarchy. As part of the issuance of the May 2023 Notes, the Company also issued warrants which were determined to be freestanding, liability classified and measured at fair value. Refer below. The Company recorded both the May 2023 Notes and warrants issued as part of the 2023 Financing at fair value upon issuance, which totaled the amount of proceeds received on an aggregate basis, and subsequently remeasured the financial instruments to fair value at each reporting date.The assumptions that the Company used to determine the fair value of the May 2023 Notes as of the issuance date are as follows: F-19 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Â Â As of Issuance Date Â Probability of qualified financing* Â Â 60 % Volatility Â Â 85 % Class C Preferred Share Price (CAD) Â $ 2.074 Â Liquidity price at conversion of listing event** Â $ 8.42 Â Fair value of common share at conversion of listing event** Â $ 10.25 Â Discount rate*** Â Â 40.8 % Expected time to respective scenarios Â 0.3Â years Â Â * The probability represents the cumulated probabilities of conversion at various dates before maturity. The probability includes the probability of a SPAC transaction (which corresponds to a listing event for the 2023 Notes).** The liquidity price at the conversion of a listing event represents the conversion price of the 2023 Notes upon the merger with FEAC, and the fair value per common share at conversion of a listing event represents the price per share of the Newco upon the merger with FEAC, as set forth in the Merger Agreement.*** Discount rate includes credit risk, discount for lack of marketability and other factors considered in the model.Immediately prior to the conversion and exchange of the May 2023 Notes as part of the Reverse Recapitalization, the notes were remeasured to a fair value of $93.3 million. The fair value immediately prior to the settlement was determined using the quoted market price of $21.70 per share for the FEAC common shares on the close of business on October 31, 2023, which was determined to be fair value of the common share on settlement, and considering the 4,298,463 shares of the Company issued to the holders of the May 2023 Notes upon the consummation of the Reverse Recapitalization. The following table provides a summary of the change in the estimated fair value of the Companyâ€™s 2023 Notes for the year ended October 31, 2023. Upon the close of the Reverse Recapitalization the 2023 Notes were exchanged for common shares of the Company, resulting in an extinguishment of the 2023 Notes. See Note 3, Reverse Recapitalization and Note 10, Convertible Debentures.Â Â Total Â Balance as of October 31, 2022 Â $ â€” Â Issuance of May 2023 Notes Â Â 37,043 Â Change in fair value of May 2023 Notes Â Â 56,212 Â Settlement of 2023 Notes upon the consummation of the ReverseÂ Â Â Recapitalization Â Â (93,255) Balance as of October 31, 2023 Â $ â€” Â Â Warrant Liabilities Prior to the consummation of the Reverse Recapitalization, Old enGene issued warrants to purchase redeemable convertible preferred shares as part of the issuance of certain redeemable convertible preferred shares, convertible debentures, and the term loan (the â€œPreferred Share Warrantsâ€). Upon the close of the Reverse Recapitalization, the Preferred Share Warrants were surrendered for no consideration and the fair value was determined to be zero. The Company estimated the fair value of its Preferred Share Warrant liabilities using a Modified Black-Scholes option-pricing model, which included assumptions that are based on the individual characteristics of the Preferred Share Warrants on the valuation date, and assumptions related to the fair value of the underlying redeemable convertible preferred shares, expected volatility, expected life, dividends, risk-free interest rate and discount for lack of marketability (â€œDLOMâ€). Due to the nature of these inputs, the Preferred Share Warrants are considered a Level 3 liability. The weighted average expected life of the Preferred Share Warrants was estimated based on the weighting of scenarios considering the probability of different terms up to the contractual term of 10 years in light of the expected timing of a future exit event, which includes a SPAC transaction. The Company determines the expected volatility based on an analysis of reported data for a group of guideline companies that have issued instruments with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. The risk-free interest rate is determined by reference to the Canadian treasury yield curve in effect at the time of measurement of the warrant liabilities for time periods approximately equal to the weighted average expected life of the warrants. The Company has not paid, and did not anticipate paying, cash dividends on its redeemable convertible preferred shares; therefore, the expected dividend yield is assumed to be zero. F-20 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Because there was no public market for the underlying redeemable convertible preferred shares, the Company determined their fair value based on third-party valuations. Initially, the estimated enterprise equity value of the Company was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Companyâ€™s various securities of its capital structure using an option pricing method, or â€œOPMâ€, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another. Significant assumptions used in the OPM to determine the fair value of redeemable convertible preferred shares include volatility, DLOM, and the expected timing of a future liquidity event such as an IPO, SPAC transaction or sale of the Company, in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios.In addition to considering the results of these valuations, the Company considered various objective and subjective factors to determine the fair value of the Company's preferred shares as of each valuation date, including the prices at which the Company sold redeemable convertible preferred in the most recent transactions, external market conditions, the progress of the Company's research and development programs, the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results, and the lack of an active public market for the Company's redeemable convertible preferred shares, among other factors.Â The warrants issued by Old enGene as part of the 2023 Financing (the â€œ2023 Warrantsâ€) were concluded to be freestanding, liability classified instruments upon issuance, which were subsequently reclassified to equity upon the consummation of the Reverse Recapitalization. See Note 10. The Company estimated the fair value of the 2023 Warrants based on the underlying quoted market price of the FEAC public warrants, prior to the close of the Reverse Recapitalization. The 2023 Warrants were classified as a Level 2 measurement given they are substantially similar to FEAC public warrants. The price used to value the 2023 Warrants as of the issuance date and immediately prior to the consummation of the Reverse Recapitalization was $0.53 and $0.74, per warrant, respectively, which represented the quoted market price of the FEAC public warrants on each date.The following table provides a summary of the change in the estimated fair value of the Companyâ€™s warrant liabilities for the year ended October 31, 2023:Â Â Total Â Balance as of October 31, 2022 Â Â 11,456 Â Warrant liability recognized upon issuance of May 2023 Notes Â Â 1,420 Â Change in fair value of warrant liabilities Â Â (10,849) Foreign exchange rate translation adjustment Â Â (44) Reclassification of 2023 Warrants to equity upon consummationÂ Â Â of the Reverse Recapitalization Â Â (1,983) Balance as of October 31, 2023 Â $ â€” Â Â F-21 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â 5. Marketable securitiesAs of October 31, 2024, the marketable securities consisted of the following:Â Â October 31, 2024 Â Description Â Amortized Cost Â Â Unrealized Holdings Gains Â Â Unrealized Holdings Losses Â Â Aggregate Fair Value Â Cash equivalents and short-term investments: Â Â Â Â Â Â Â Â Â Â Â Â Money market funds, included in cash and cash equivalents Â $ 121 Â Â $ â€” Â Â $ â€” Â Â $ 121 Â US treasury Â Â 145,832 Â Â Â 12 Â Â Â (30) Â Â 145,814 Â Government agency securities Â Â 23,714 Â Â Â 3 Â Â Â (8) Â Â 23,709 Â Total cash equivalents and short-term investments Â $ 169,667 Â Â $ 15 Â Â $ (38) Â $ 169,644 Â Long-term investments Â Â Â Â Â Â Â Â Â Â Â Â US treasury Â Â 49,931 Â Â Â â€” Â Â Â (306) Â Â 49,625 Â Government agency securities Â Â 9,972 Â Â Â â€” Â Â Â (74) Â Â 9,898 Â Total long-term investments Â $ 59,903 Â Â $ â€” Â Â $ (380) Â $ 59,523 Â Total Â $ 229,570 Â Â $ 15 Â Â $ (418) Â $ 229,167 Â As of October 31, 2024, all marketable securities held by the Company had remaining contractual maturities of one year and less, except for U.S. government securities that had maturities of one to two years.As of October 31, 2024, the Company held 31 securities, 21 of which were in unrealized loss position. All investments in an unrealized loss position were in this position for less than 12 months. The Company does not intend to sell its investments before recovery of the amortized cost basis of its debt securities at maturity and no allowance for credit losses was recorded as of October 31, 2024 because the decline in fair value below amortized cost is not related to credit losses. Securities are evaluated at the end of each reporting period. The unrealized losses on U.S. Treasury and Government agency securities range from 0-1% of their amortized cost.Accrued interest receivable on the Company's available-for-sale debt securities totaled $0.7 million and zero as of October 31, 2024 and 2023, respectively, and was presented within prepaids and other current assets on the Company's consolidated balance sheets. No accrued interest receivable was written off during the twelve months ended October 31, 2024 or 2023.There were no material realized gains or losses recognized on the sale or maturity of available-for-sale securities during the years ended October 31, 2024 or 2023. 6. Property and Equipment, NetAs of October 31, 2024 and 2023, property and equipment, consisted of the following: Â Â October 31, Â Â October 31, Â Â Â 2024 Â Â 2023 Â Lab equipment Â $ 2,191 Â Â $ 1,779 Â Computer equipment Â Â 62 Â Â Â 269 Â Computer software Â Â 146 Â Â Â 70 Â Office furniture Â Â 141 Â Â Â 69 Â Leasehold improvements Â Â 239 Â Â Â 129 Â Property and equipment Â Â 2,779 Â Â Â 2,316 Â Less: Accumulated depreciation and amortization Â Â 1,610 Â Â Â 1,727 Â Property and equipment, net Â $ 1,169 Â Â $ 589 Â Â Depreciation and amortization expense related to property and equipment was $0.3 million and $0.2 million for the year ended October 31, 2024 and 2023, respectively. 7. Accrued Expenses and Other Current LiabilitiesAs of October 31, 2024 and 2023, accrued expenses and other current liabilities consisted of the following:Â F-22 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Â October 31, Â Â October 31, Â Â 2024 Â Â 2023 Â Accrued research and development expenses Â $ 3,773 Â Â $ 759 Â Employee compensation and related benefits Â Â 3,475 Â Â Â 814 Â Accrued financing costs (1) Â Â 3,831 Â Â Â 613 Â Professional fees Â Â 824 Â Â Â 1,201 Â Accrued income taxes payable Â Â - Â Â Â 39 Â Other Â Â 225 Â Â Â 113 Â Total accrued expenses and other current liabilities Â $ 12,128 Â Â $ 3,539 Â Â (1) The presentation of accrued financing costs as of October 31, 2023 has been updated to conform with presentation as of October 31, 2024. Â 8. License Agreement and Clinical Research OrganizationLicense Agreement â€“ Nature Technology CorporationOn April 10, 2020, the Company entered into a Non-Exclusive License Agreement (the â€œLicense Agreementâ€) with Nature Technology Corporation (â€œNTCâ€) whereby the Company licenses certain rights to NanoplasmidTM technology from NTC for commercialization. Under the terms of the License Agreement, NTC granted to the Company and its affiliates a non-exclusive, royalty-bearing, sublicensable license to research, have researched, develop, have developed, make, have made, use, have used, import, have imported, sell, offer to sell, and have sold or offered for sale any product in the defined license field. Unless terminated earlier, the NTC license agreement will continue until no valid claim of any licensed patent exists in any country. The Company can voluntarily terminate the license agreement with prior notice to NTC.The Company paid NTC an initial, upfront fee of $50 thousand which was recorded as research and development expense upon entering into the License Agreement. Beginning on the first anniversary of the effective date of the License Agreement and on each subsequent anniversary, the Company is required to pay NTC a $50 thousand annual maintenance fee. The Company is also required to make a payment to NTC of $50 thousand upon assigning the License Agreement to a third party.The License Agreement provides for a one-time payment of $50 thousand for the first dose of a milestone product, as defined in the License Agreement, in the first patient in a Phase 1 clinical trial or, if there is no Phase 1 clinical trial, in a Phase 2 clinical trial, as well as a one-time payment of $450 thousand upon regulatory approval of a milestone product by the U.S. Food and Drug Administration. The first milestone related to the first dose of a milestone product, was achieved during the year ended October 31, 2021. The second milestone, regulatory approval of a milestone product, has not yet been achieved as of the year ended October 31, 2024. The Company is also required to pay NTC a royalty percentage in the low single digits of the aggregate net product sales in a calendar year by the Company, its affiliates or sublicensees on a product-by-product and country-by-country basis, as long as the composition or use of the applicable product is covered by a valid claim in the country where the net sales occurred. Royalty obligations under the license agreement will continue until the expiration of the last valid claim of a licensed patent covering such licensed product in such country.In the event that the Company or any of its affiliates or sublicensees manufactures any Good Manufacturing Practice (â€œGMPâ€) lot of a product, then the Company or any such affiliate or sublicensee will be obligated to pay NTC an amount per manufactured gram of GMP (or its equivalent) lot of product, which varies based on the volume manufactured. The payment will expire on a product-by-product basis upon receipt of regulatory approval to market a product in any country in the licensed territory.During each of the years ended October 31, 2024 and 2023, the Company incurred $50 thousand of expenses related to the annual maintenance fee under the License Agreement which is recorded within research and development expenses. 9. Notes Payable2021 Loan and Security AgreementOn December 30, 2021, the Company entered into a Loan and Security Agreement (the â€œPrior Loan Agreementâ€) with Hercules Capital, Inc. (â€œHerculesâ€ or the â€œLenderâ€) for the issuance of a term loan facility with an aggregate principal amount of up to $20.0 million (the â€œPrior Term Loanâ€). The Prior Loan Agreement provided for (i) an initial term loan advance of $7.0 million, which closed on December 30, 2021, (ii) subject to the achievement of certain clinical milestones (â€œClinical Milestoneâ€), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $4.0 million from F-23 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â the achievement of the Clinical Milestone through June 15, 2022, which was drawn in June 2022, and (iii) subject to the achievement of certain financial milestones (â€œFinancial Milestoneâ€), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $9.0 million from achievement of the Financial Milestone through December 15, 2022, which was not achieved. The Company is required to pay an end of term fee (â€œPrior Term Loan End of Term Chargeâ€) equal to 6.35% of the aggregate principal amount of the Prior Term Loan advances upon repayment.The Prior Term Loans were scheduled to mature on July 1, 2025, with no option for extension (the â€œPrior Term Loan Maturity Dateâ€).The Prior Term Loan accrued interest at an annual rate equal to the greater of (i) 8.25% plus the prime rate of interest as reported in the Wall Street Journal minus 3.25% and (ii) 8.25% provided, that, from and after the date the Company achieves the financial milestone, as defined within the agreement, the reference to 8.25% in clauses (i) and (ii) is reduced to 8.15%. Borrowings under the Prior Term Loan are repayable in monthly interest-only payments through June 2023. After the interest-only payment period, borrowings under the Prior Term Loan are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. At the Companyâ€™s option, the Company may elect to prepay all, but not less than all, of the outstanding term loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% of the principal amount outstanding if the prepayment occurs in any of the first twelve months following the closing date of the last draw down; (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the closing date of the last draw down, but on or prior to twenty-four months following the closing date of the last draw down; and 1.0% of the principal amount outstanding at any time thereafter but prior to the Maturity Date.In connection with the Prior Term Loan, the Company granted Hercules a security interest senior to any current and future debts and to any security interest, in all of the Companyâ€™s right, title, and interest in, to and under all of the Companyâ€™s property and other assets, and certain equity interests and accounts of Old enGene, subject to limited exceptions including the Companyâ€™s intellectual property. The Prior Loan Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company.The debt discount and issuance costs under the Prior Term Loan were accreted to the principal amount of debt and being amortized from the date of issuance through the Maturity Date to interest expense using the effective-interest rate method. The effective interest rate of the outstanding debt under the Prior Loan Agreement was approximately 18.3% as of October 31, 2023. The Company borrowed $11.0 million under the Prior Loan Agreement and incurred $1.1 million of debt discount and issuance costs inclusive of facilities fees, legal fees, Prior Term Loan End of Term Charge and initial fair value of the warrants under the Prior Term Loan.Old Hercules WarrantsUnder the Prior Loan Agreement, the Company agreed to issue to Hercules warrants (the â€œOld Hercules Warrantsâ€) to purchase a number of shares of Old enGeneâ€™s redeemable convertible preferred shares at the exercise price equal to 2.5% of the aggregate amount of the Prior Term Loans that are funded, as such amounts are funded. On the first tranche closing, Old enGene issued a warrant to purchase 84,714 Class C Preferred Shares which were determined to have a fair value of $34 thousand upon issuance. On the second tranche closing, in June 2022, Old enGene issued an additional warrant to purchase 48,978 Class C Preferred Shares which were determined to have a fair value of $23 thousand upon issuance. The fair value of the Old Hercules Warrant values were initially recorded as a discount to the Prior Term Loan principal balance and are being amortized to interest expense using the effective interest method over the life of the Prior Term Loan. The Old Hercules Warrants were initially exercisable for a period of ten years from the date of the issuance of each warrant at a per-share exercise price equal to $2.632 Canadian dollars, subject to certain adjustments as specified in the warrants. In addition, the Company has granted to the holders of the Old Hercules Warrants certain registration rights on a pari passu basis with the holders of outstanding preferred shares and warrants to purchase preferred shares.The Company accounted for the warrants as a liability prior to the consummation of the Reverse Recapitalization since they were indexed to Old enGeneâ€™s redeemable convertible preferred shares that were classified as temporary equity. The Company remeasured the fair value of the warrants at each reporting date with changes being recorded as a change in the fair value of the warrant liabilities.Upon the close of the Reverse Recapitalization, the Old Hercules Warrants, along with all other warrants to purchase shares of Old enGene's redeemable convertible preferred shares, were surrendered for no consideration. F-24 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Amended Loan and Security AgreementOn December 22, 2023 (the â€œHercules Closing Dateâ€), the Company entered into an amended and restated loan and security Agreement (the â€œAmended Loan Agreementâ€), with Hercules, as agent and lender, and the several banks and other financial institutions or entities from time to time parties thereto (with Hercules, the â€œLendersâ€). The Amended Loan Agreement amends and restates in its entirety the Prior Loan Agreement with Hercules dated December 30, 2021.As of October 31, 2024, the Amended Loan Agreement provides for a term loan facility of up to $50.0 million available in multiple tranches (the â€œTerm Loanâ€), as follows: (i) an initial term loan advance (the â€œTranche 1 Advanceâ€) that was made on the Tranche 1 Advance closing of $22.5 million, approximately $8.6 million of which was applied to refinance in full the term loans outstanding under the Prior Loan Agreement, (ii) subject to the achievement of the specified Interim Milestone (the â€œInterim Milestoneâ€), which includes no default or event of default, delivery of written notice to the Lenders that the Company has conducted an analysis of interim efficacy of data from the clinical evaluation of detalimogene in the Phase 2 clinical study, and satisfaction of certain other conditions precedent, a right of the Company to request that the Lenders make additional term loan advances to us in an aggregate principal amount of up to $7.5 million from the date of achievement of the Interim Milestone through the earlier of (x) 60 days following the achievement of the Interim Milestone and (y) March 31, 2025, and (iii) an uncommitted tranche subject to the Lendersâ€™ investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time up to and including the Amortization Date (defined below) that the Lenders make additional term loan advances to the Company in an aggregate principal amount of up to $20.0 million. The Company is required to pay upon the earlier of January 1, 2028 (the â€œMaturity Dateâ€) or payment in full of the Term Loans, an end of term fee equal to 5.50% of the aggregate principal amount of the Term Loans (the â€œEnd of Term Chargeâ€). The Company is also required to pay on July 1, 2025 or, if earlier, the date the Company prepays the Term Loans, $0.7 million representing the Prior Term Loan End of Term Charge (the Prior Term Loan End of Term Charge and End of Term Charge, collectively the â€œEnd of Term Chargesâ€).The Term Loans mature on January 1, 2028, with no option for extension.The Term Loan bears cash interest payable monthly at an annual rate equal to the greater of (a) the prime rate of interest as reported in the Wall Street Journal plus 0.75% (capped at 9.75%) and (b) 9.25%. The Term Loan also bears additional payment-in-kind interest at an annual rate of 1.15%, which is added to the outstanding principal balance of the Term Loan on each monthly interest payment date. Borrowings under the Amended Loan Agreement are repayable in monthly interest-only payments through the â€œAmortization Dateâ€, which is either: (x) July 1, 2025 or (y) if the Interim Milestone is achieved and there has been no default, January 1, 2026, or (z) if the Interim Milestone and certain clinical milestones are achieved and there has been no default, July 1, 2026. After the Amortization Date, the outstanding Term Loans and interest shall be repayable in equal monthly payments of principal and accrued interest until the Maturity Date. The effective interest rate of the Term Loan was 11.63% as of October 31, 2024.At the Company's option, the Company may elect to prepay all, but not less than all, of the outstanding Term Loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% of the principal amount outstanding if the prepayment occurs in any of the first twelve months following the Closing Date; (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the Closing Date but on or prior to twenty-four months following the Closing Date; and (iii) 1.0% of the principal amount outstanding if prepayment occurs at any time thereafter but prior to the Maturity Date.In connection with the Amended Loan Agreement, the Company granted Hercules a security interest senior to any current and future debts and to any security interest in all of the Companyâ€™s right, title, and interest in, to and under all of the Companyâ€™s property and other assets, subject to limited exceptions including the Companyâ€™s intellectual property.The Amended Loan Agreement contains negative covenants that, among other things and subject to certain exceptions, could restrict the Company's ability to incur additional liens, incur additional indebtedness, make investments, including acquisitions, engage in fundamental changes, sell or dispose of assets that constitute collateral, including certain intellectual property, pay dividends or make any distribution or payment on or redeem, retire or purchase any equity interests, amend, modify or waive certain material agreements or organizational documents and make payments of certain subordinated indebtedness. The Amended Loan Agreement also contains certain events of default and representations, warranties and non-financial covenants of the Company. The Company is in compliance with the financial covenants at October 31, 2024.The Company accounted for the Amended Loan Agreement as an extinguishment of the Prior Term Loan. As a result of the extinguishment, the Company recorded a loss of $0.4 million as a component within other income and expense in the Company's consolidated statement of operations during the year ended October 31, 2024, which represented the difference between the reacquisition F-25 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â price of the debt, including fees and the initial fair value of the warrants paid directly to the lender, and the carrying value of the Prior Term Loan at the time of extinguishment.As of October 31, 2024, the Company had borrowed $22.5 million under the Amended Loan Agreement and incurred $2.2 million of debt discount and issuance costs inclusive of legal fees and End of Term Charges under the Term Loan.First Amendment to Amended and Restated Loan and Security AgreementOn December 18, 2024, the Company entered into the First Amendment to Amended and Restated Loan and Security Agreement with Hercules, which amended the Amended Loan Agreement. See Note 19, Subsequent Events for additional information. Hercules Common Share WarrantsIn connection with the Amended Loan Agreement, the Company also agreed to issue to the Lenders in connection with each advance of Term Loans warrants to purchase that number of the Companyâ€™s common shares, as shall be equal to 2% of the aggregate principal amount of such Term Loan advance divided by the Warrants per share exercise price of $7.21 (which exercise price equals the ten-day volume weighted average price for the ten (10) trading days preceding the Hercules Closing Date and is subject to customary adjustments under the terms of the Warrants) (the â€œHercules Common Share Warrantsâ€). The Hercules Common Share Warrants are exercisable for a period of seven years from issuance.Under the terms of the Amended Loan Agreement, the maximum number of Hercules Common Share Warrants and underlying Common Shares of the Company that could be issued is 138,696. On the Hercules Closing Date, the Company issued to the Lenders 62,413 Hercules Common Share Warrants in connection with the Tranche 1 Advance of the Term Loans (the â€œClosing Date Warrantsâ€). The Closing Date Warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Companyâ€™s Common Shares as prescribed by ASC 815. Upon entering into the Amended Loan Agreement, $0.3 million of the total $22.5 million Tranche 1 Advance was allocated to the warrants, on a relative fair value basis, and recorded within additional paid in capital.Subsequently issued Hercules Common Share Warrants shall be substantially in the form of the Closing Date Warrants. Under the terms of the Amended Loan Agreement, the maximum number of Hercules Common Share Warrants and resultant underlying common shares of the Company that could be issued is 138,696 (i.e. 2% of the $50.0 million total commitment amount divided by the exercise price of $7.21 price specified in the Closing Date Warrant), assuming no adjustments are made under the terms of the Hercules Common Share Warrants and further assuming the full amount of Term Loans are drawn.As of October 31, 2024 and 2023, the carrying value of the Term Loan consists of the following:Â Â October 31, 2024 Â Â October 31, 2023 Â Note payable, including End of Term Charge Â $ 24,663 Â Â $ 10,144 Â Debt discount, net of accretion Â Â (1,673) Â Â (474) Accrued interest Â Â 182 Â Â Â 108 Â Note payable, net of discount Â $ 23,172 Â Â $ 9,778 Â Â As of October 31, 2024, the Company classified $0.7 million of the note payable as current, which represents the back-end fee associated with the refinancing of the Prior Term Loan. As of October 31, 2023, the Company classified $0.6 million of the note payable as current, which represents the principal payments due and amortization of the debt discount between October 31, 2023 and the date the Term Loan was amended in December 2023, as the debt was refinanced on a long-term basis in the subsequent event period. During the years ended

October 31, 2024 and 2023, the Company recognized $2.2 million and $1.8 million of interest expense related to the Amended Loan Agreement, respectively, of which $0.6 million and $0.4 million was related to the amortization of the debt discount, respectively.Through October 31, 2024, the Company borrowed $22.5 million under the Amended Loan Agreement and incurred $2.2 million of debt discount and issuance costs inclusive of facility fees, legal fees, End of Term Charge and initial fair value of the warrants.As of October 31, 2024, the estimated future principal payments due under the Loan Agreement, including the contractual End of Term Charge, are as follows: F-26 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Â Â Note PrincipalPayments Â 2025 Â $ 699 Â 2026 Â Â 8,417 Â 2027 Â Â 10,987 Â 2028 Â Â 5,161 Â Total principal payments, including End of Term Charge Â Â 25,264 Â Â As of October 31, 2024, based on borrowing rates available to the Company for loans with similar terms and consideration of the Companyâ€™s credit risk, the carrying value of the Companyâ€™s variable interest rate debt, excluding unamortized debt issuance costs, approximates fair value.April 2023 NotesOn April 4, 2023, Old enGene entered into a note purchase agreement (the â€œApril 2023 Notesâ€) for a principal amount of $8.0 million with Merck Lumira Biosciences Fund, L.P., Merck Lumira Biosciences Fund (Quebec), L.P., Lumira Ventures III, L.P., Lumira Ventures III (International), L.P., Lumira Ventures IV, L.P., Lumira Ventures IV (International), L.P., Fond de solidaritÃ© des travailleurs du QuÃ©bec (F.T.Q.), and Forbion Capital Fund III Cooperatief U.A. (collectively the â€œApril 2023 Investorsâ€). The April 2023 Notes had an interest free period of 45 days from the date of issuance, and commencing on the 46th day, began to accrue interest at a rate of 15% per annum. The April 2023 Notes were classified as current as they matured on the earlier of (i) July 31, 2023; or (ii) the date the Company completes a qualified financing, as defined within the April 2023 Notes as a financing pursuant to which the Company sells convertible promissory notes, warrants, preferred shares, common shares, or a combination thereof of the Company for an aggregate amount of at least $20.0 million. Upon the completion of the 2023 Financing (as defined below) in May 2023, Old enGene issued convertible debentures and warrants of Old enGene to the April 2023 Note investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing, as repayment of the April 2023 Notes.The Company elected the fair value option of accounting for the April 2023 Notes. The Company recorded the April 2023 Notes at fair value upon the date of issuance, which was determined to be $8.0 million. Given the short period of time that the April 2023 Notes were outstanding, no change in fair value was recorded during the three months ended April 30, 2023. The April 2023 Notes were extinguished in May 2023 as part of the issuance of the May 2023 Notes. See Note 10, Convertible Debentures. 10. Convertible DebenturesOld enGene had issued convertible debentures to various investors. There was no outstanding principal, accrued interest, and unamortized deferred financing costs of the convertible debentures recorded on the balance sheet as of October 31, 2024 and October 31, 2023, as the convertible debentures were converted and exchanged for common shares of the Company or repaid upon the closing of the Reverse Recapitalization. See Note 3, Reverse Recapitalization.BDC NotesIn September 2020, Old enGene issued a convertible debenture to the Business Development Bank of Canada (â€œBDCâ€) in the amount of $2.2 million (the â€œBDC Notesâ€). The debt bears interest at rate of 8% per annum and had an initial maturity date of September 28, 2023. In December 2021 Old enGene amended the agreement which resulted in the maturity date extending to September 29, 2025. The BDC Notes were convertible at the option of the holder into Old enGene's Class B redeemable convertible preferred shares at a price of 80% of the price paid per share in qualified financing, as defined within the BDC convertible debenture agreement. The issuance of the Prior Term Loan in 2021 met the definition of a qualified financing per the BDC convertible debenture agreement. As the conversion option was not exercised upon the issuance of the Prior Term Loan, the conversion rights upon a qualified financing were waived. There were optional conversion options that existed if Old enGene is in default, or in the event of certain liquidation events, as defined within the BDC Notes, which allow for conversion of the BDC Note into the most senior share outstanding at the time of the event. If a liquidation event, as defined within the BDC Note agreement, and which included a SPAC transaction, is consummated after a qualified financing, and optional conversion is not elected, the Company is required to pay the investor in cash, the outstanding principal and the accrued but unpaid interest and in addition an amount equal to 20% of the principal. Upon issuance of the BDC Notes, the Company identified embedded derivatives related to the equity conversion features and liquidity event repayment features which required bifurcation as a single compound derivative instrument. The Company estimated the F-27 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â fair value of the embedded derivative liabilities upon issuance at $0.2 million. The Company remeasured the fair value of the embedded derivatives in effect at each reporting period, with the subsequent changes in the fair value of the derivative being recognized in changes in fair value of derivatives within the Companyâ€™s consolidated statements of operations and comprehensive loss. During the year ended October 31, 2023, the Company recorded a change in fair value of the convertible debentures embedded derivative liability associated with the BDC Note of $0.3 million. Total interest expense, including the amortization of debt discounts, of $0.3 million was recorded for the year ended October 31, 2023. Upon the close of the Reverse Recapitalization the Company repaid the BDC Note, including the liquidity event repayment amount, resulting in full settlement of the note and extinguishment of the embedded derivative liability. The estimated fair value of the embedded derivative liabilities at October 31, 2022 was $0.3 million, resulting in $0.3 million of expense recorded as change in fair value of convertible debentures embedded derivative liabilities in the consolidated statement of operations and comprehensive loss for the year ended October 31, 2022. Total interest expense, including the amortization of debt discounts, was $0.4 million for the year ended October 31, 2022. As part of the issuance of the BDC Notes, the Company incurred an aggregate of $36 of debt issuance costs of which a portion were recorded as a reduction of the carrying value of the BDC Notes, and a portion was allocated to the embedded derivative liabilities which were expensed as incurred.On May 12, 2023, the Company consented to certain modifications of the BDC Notes pursuant to which the Company will be required on the Closing Date to repay in cash (i) the outstanding principal and the accrued but unpaid interest; and (ii) an amount equal to 20% of the principal.Upon the close of the Reverse Recapitalization, the Company repaid the BDC Note in full, resulting in a loss on extinguishment of $9 thousand due to the difference between the repayment amount and the carrying amount of the debenture and fair value of the embedded derivative lability at the time of repayment. 2022 NotesDuring the year ended October 31, 2022, Old enGene issued convertible debentures for an aggregate amount of $18.4 million on October 20, 2022 (the â€œ2022 Notesâ€). The 2022 Notes had an initial maturity that is the later of (i) three years from the date of issuance; or (ii) the maturity date of the Prior Term Loan. See Note 8, License Agreement and Clinical Research Organization. The 2022 Notes bear interest at 10% per annum commencing on the date of issuance. The 2022 Notes are automatically convertible into common shares or redeemable convertible preferred shares of Old enGene upon certain events. Upon the close of the Reverse Recapitalization, the 2022 Notes were converted into 2,081,359 Common Shares of the Company.Upon issuance of the 2022 Notes, the Company identified embedded derivatives related to the equity conversion features which required bifurcation as a single compound derivative instrument. The Company estimated the fair value of the embedded derivative liabilities upon issuance at $3.5 million. Given the close proximity between the issuance date of the notes and the Companyâ€™s year ended October 31, 2022, no change in fair value was recorded related to the embedded derivative liabilities identified as part of the issuance of the 2022 Notes. During the year ended October 31, 2023, the Company recorded a change in fair value associated with the 2022 Notes embedded derivative liability of $21.2 million in the consolidated statement of operations and comprehensive loss for the year ended October 31, 2023. As of October 31, 2023 no embedded derivative liability is recorded for the 2022 Notes as they converted to shares of the Company upon the consummation of the Reverse Recapitalization. Total interest expense, including the amortization of debt discounts, was $2.8 million for the year ended October 31, 2023, respectively. As part of the issuance of the 2022 Notes, the Company incurred an aggregate of $44 thousand of debt issuance costs of which a portion were recorded as a reduction of the carrying value of the 2022 Notes, and a portion was allocated to the embedded derivative liabilities which were expensed as incurred.On May 16, 2023, the Company agreed to certain modifications of the 2022 Notes having an aggregate principal amount of $18.4 million (the â€œAmended 2022 Financingâ€), which included a change in the definition of the maturity date by allowing an extension of the maturity date upon election of a noteholder majority, increasing the percentage required for a noteholder majority, and modifying terms of certain conversion options. The amendments to the 2022 Notes did not result in the addition or termination of any substantive conversion terms, and the amendment to the 2022 Notes was determined to be non-substantial and was accounted for as a modification. In addition, as part of the May 2023 Financing, the holders of the 2022 Notes which participated in the 2023 Financing received warrants to purchase common shares of the Company. The fair value of the warrants at the time of issuance to the holders of the 2022 Notes was determined to be $0.5 million and was recorded as reduction of the carrying value of the 2022 Notes as part of the modification, which is being amortized to interest expense through the maturity date of the 2022 Notes.On October 31, 2023 upon the close of the Reverse Recapitalization, the 2022 Notes were converted into 2,081,359 Common Shares of the Company. The Company accounted for the conversion as an extinguishment and recorded a loss on extinguishment of F-28 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â $3.1 million, relating to the difference between the fair value of the common shares issued and the carrying value of the 2022 Notes and fair value of the embedded derivative liability at the time of conversion. May 2023 Notes On May 16, 2023, concurrently with the execution and delivery of the Merger Agreement, Old enGene entered into agreements pursuant to which it agreed to issue new convertible notes and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in repayment of the April 2023 Notes in an aggregate amount of $8.0 million (collectively, the â€œMay 2023 Notesâ€ and, together with the warrants purchased concurrently, the â€œ2023 Financingâ€; the 2023 Financing together with the Amended 2022 Financing, the â€œConvertible Bridge Financingâ€). The 2023 Financing occurred in two separate issuances with $28.0 million issued in May 2023 for $20.0 million in cash and $8.0 million in repayment of the April 2023 Notes, and an additional $10.0 million issued in June 2023 for $10.0 million in cash, of which Forbion Growth Sponsor FEAC I B.V. funded an aggregate amount of $20.0 million of the total $38.0 million. The May 2023 Notes issued as part of the 2023 Financing, if not converted, have an initial maturity date of October 20, 2025 and are to accrue interest at 10% per annum, which is payable upon maturity. The warrants issued as part of the 2023 Financing were for the purchase of common shares of Old enGene. The 2023 Warrants were only to become exercisable upon the completion of the merger. Upon the close of the Reverse Recapitalization, the 2023 Warrants were exchanged for 2,679,432 warrants of the Company and have the same terms as the public warrants issued upon the FEAC initial public offering, with an exercise price of $11.50, and which will expire five years after the completion of the merger.The warrants issued as part of the 2023 Financing were concluded to be liability classified upon issuance, as they failed the fixed for fixed criteria that is required for a contract to be considered indexed to the Companyâ€™s own stock as prescribed by ASC 815. The terms of the warrants initially required the Company to issue a variable number of shares until the PIPE Financing was executed, at which time the number of warrants became fixed. The 2023 Warrants were initially and subsequently measured at fair value with any changes in fair value recorded as a component of other income and expense within the change in fair value of warrant liabilities. See Note 3, Reverse Recapitalization. Upon the execution of the PIPE Financing and consummation of the Reverse Recapitalization, the warrants were reclassified to equity as the number of warrants became fixed and it was determined that the warrants met the fixed for fixed criteria that is required for a contract to be considered indexed to the Companyâ€™s own stock as prescribed by ASC 815.The Company elected the fair value option of accounting for the May 2023 Notes. The Company recorded May 2023 Notes at fair value upon the date of issuance. At inception the fair value of the May 2023 Notes was determined to be $37.0 million and the fair value of the related warrants was determined to be $1.4 million, of which $0.5 million related to the fair value of the warrants issued to the holders of the 2022 Notes, as described above. During the year ended October 31, 2023, the Company recorded a change in fair value of the May 2023 Notes of $56.2 million. The Company incurred $0.8 million of debt issuance costs associated with the May 2023 Notes which have been expensed and are included within general and administrative expenses. See Note 3, Reverse Recapitalization.On October 31, 2023 upon the close of the Reverse Recapitalization, the 2023 Notes were converted into 4,298,463 common shares of the Company. The Company accounted for the conversion as an extinguishment, with no gain or loss recorded on extinguishment as the fair value of the common shares issued was determined to equal the fair value of the 2023 Notes at the time of conversion. 11. Redeemable Convertible Preferred SharesAs of October 31, 2022, Old enGeneâ€™s Articles of Amendment had an unlimited number of authorized shares of each class of redeemable convertible preferred shares. Class A Redeemable Convertible Preferred SharesOn July 26, 2013, the Company entered into a subscription agreement (the â€œClass A Agreementâ€) with multiple investors, whereby the Company agreed to sell to the investors an initial aggregate amount of 610,333 Class A redeemable convertible preferred shares at a price of $1.5929 ($1.63845 CAD) per share for total aggregate proceeds of $1.0 million (the â€œClass A Initial Closingâ€). Included within the Class A Agreement were three additional future tranche obligations (the â€œClass A Second Tranche,â€ â€œClass A Third Trancheâ€ and â€œClass A Fourth Trancheâ€) for the Company to issue and sell shares of Class A redeemable convertible preferred shares upon the achievement of certain milestone events. Only the Class A Second Tranche closed under the Class A Agreement. The Class A Second Tranche obligated the Company to sell and the Class A Investors to purchase 1,830,999 shares of Class A redeemable convertible preferred shares at a price of $1.56967 ($1.63845 CAD) per share for total proceeds of $2.9 million, upon the establishment of the F-29 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Companyâ€™s headquarters in Montreal Quebec and completion of experiments required to bolster a patent application for dually-derivatized chitosan (the â€œSecond Closing Milestone Eventâ€), which occurred in 2013. Additionally, upon completing the Class A redeemable convertible preferred share financing, convertible notes of the Company held by multiple investors converted into Class A redeemable convertible preferred shares. Class B Redeemable Convertible Preferred SharesOn January 6, 2015, the Company entered into a subscription agreement (the â€œClass B Agreementâ€) with multiple investors, where the Company agreed to sell to the investors an initial aggregate amount of 2,758,221 Class B redeemable convertible preferred shares at a price of $1.85032 ($2.17532 CAD) per share for total proceeds of $5.1 million (the â€œClass B Initial Closingâ€). Included within the Class B Agreement were two additional closings (the â€œClass B Second Tranche,â€ and the â€œClass B Third Tranche,â€ respectively) which obligated the Company to sell and Class B investors to purchase additional Class B redeemable convertible preferred shares upon certain events. The Class B Second Tranche obligated the Company to sell and the Class B Investors to purchase 1,838,815 Class B Shares at a price of $1.63419 ($2.17532 CAD) per share for total proceeds of $3.0 million and the Class B Third Tranche obligated the Company the sell and the Class B Investors to purchase 1,608,963 Class B Shares at a price of $1.63419 ($2.17532 CAD) per share for total proceeds of $2.6 million. The Class B Second Tranche and Class B Third Tranche closed on March 1, 2017.Class B-1 Redeemable Convertible Preferred SharesOn September 10, 2015, the Company entered into a Subscription Agreement (the Class â€œB-1 Agreementâ€), in which the Company was to issue 1,523,809 Class B-1 redeemable convertible preferred shares for a purchase price of $1.64367 ($2.17532 CAD) per share, resulting in aggregate proceeds of $2.5 million. During the year ended October 31, 2020, the Class B-1 redeemable convertible preferred shares converted to common shares on a 1:1 basis. Therefore, as of each of the years ended October 31, 2023, October 31, 2022, and October 31, 2021, no shares of the Class B-1 redeemable convertible preferred shares remained outstanding. The Company presented these shares within temporary equity, as they contained the same redemption features as the Class B redeemable convertible preferred shares (further described above). Upon conversion to common shares, the carrying value of the Class B-1 redeemable convertible preferred shares was reclassified to additional paid in capital within shareholdersâ€™ deficit.Class C Redeemable Convertible Preferred SharesThe Class C redeemable convertible preferred shares are issuable in series, of which an unlimited number are designated as Series 1 Class C redeemable convertible preferred shares with an issue price per share of $1.5929 ($1.63845 CAD); an unlimited number are designated as Series 2 Class C redeemable convertible preferred shares with an issue price per share of $1.85032 ($2.175315 CAD); an unlimited number are designated as Series 3 Class C redeemable convertible preferred shares with an issue price per share of $2.12376 ($2.6320 CAD); and an unlimited number are designated as Series 4 Class C redeemable convertible preferred shares that is reserved for the potential conversion of the BDC Notes, and will each have an issue price per share of $1.69901 ($2.10559 CAD).On June 30, 2021, the Company entered into a subscription agreement (the â€œClass C Agreementâ€) with multiple investors, where the Company agreed to sell to the Investors an initial aggregate amount of 3,662,813 Series 3 Class C redeemable convertible preferred shares (the â€œSeries 3 Class C Sharesâ€) at a price of $2.12376 ($2.6320 CAD) per share for total proceeds of $7.8 million (the â€œClass C Initial Closingâ€). Included within the Class C Agreement was one additional closing (the â€œClass C Second Trancheâ€) which obligated the Company to sell and Class C investors to purchase additional Class C redeemable convertible preferred shares upon the achievement of certain milestone events. The Class C Second Tranche obligated the Company to sell and the Class C investors to purchase 3,662,810 Series 3 Class C Shares at a price of $2.13192 ($2.6320 CAD) per share for total proceeds of $7.8 million. The Class C Second Tranche closed on October 29, 2021. As part of each of the Class C Initial Closing and Class C Second Tranche, each Class C investor received 3,662,813 and 3,662,810 warrants, respectively, to purchase Class C redeemable convertible preferred shares (the â€œClass C Warrantsâ€), resulting in an aggregate issued amount of 7,325,623 Class C Warrants. The Class C Warrants have an exercise price of $2.12376 ($2.6320 CAD) per share and a term of 10 years. The Class C Warrants were determined to be liabilities. The Company estimated the fair value of the warrant liabilities upon issuance and remeasured the fair value of the warrant liabilities at each reporting period, with the subsequent changes in the fair value of the warrant liabilities being recognized in changes in fair value of warrant liabilities within the Companyâ€™s consolidated statements of operations and comprehensive loss. Upon the completion of the merger with FEAC, all existing Class C Warrants of the Company will be extinguished. F-30 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Under the terms of the Class C Agreement, certain convertible notes held by various Class C investors and other investors were exchanged for an aggregate amount of 16,464,646 Class B redeemable convertible preferred shares. Additionally, upon entering into the Class C Agreement, the Company also entered into a share exchange agreement (the â€œShare Exchange Agreementâ€) with the Class A investors and the Class B investors. As part of the Share Exchange Agreement, certain of the Class A redeemable convertible preferred shares issued to Class A investors were exchanged for Series 1 Class C redeemable convertible preferred shares and certain of the Class B redeemable convertible preferred shares issued to the Class B investors were exchanged for Series 2 Class C redeemable convertible preferred shares. This exchange resulted in the derecognition of Class A and B redeemable convertible preferred shares and the recognition of Class C redeemable convertible preferred shares at the fair value of the Class C redeemable convertible preferred shares. The difference between the carrying value of the Class A and Class B redeemable convertible preferred shares and the fair value of the Class C redeemable convertible preferred shares for which they converted into was recorded within additional paid in capital and no gain or loss on extinguishment was recorded within the consolidated statements of operations and comprehensive loss. Further, the February 2020 Warrants, June 2020 Warrants, and 2021 Warrants, which consisted of warrants to purchase the Companyâ€™s Class B redeemable convertible preferred shares and were issued as part of the convertible debentures were cancelled and replaced by the terms of the Class C Warrants. The aggregate amount of outstanding warrants of 10,242,130 from the February 2020 Warrants, the June 2020 Warrants, and the 2021 Warrants converted into 10,242,130 Class C Warrants, which have an exercise price of $2.12376 ($2.6320 CAD) per share and a term expiring on February 14, 2030. Immediately prior to conversion, the warrants were marked to fair value, with the change in the fair value of the warrant liabilities being recognized in changes in fair value of warrant liabilities within the Companyâ€™s consolidated statements of operations and comprehensive loss. Upon issuance of each series of Class A, Class B, and Class C Preferred Shares, the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features. Conversion of Redeemable Convertible Preferred StockPursuant to the terms of the Merger Agreement, upon the consummation of the Reverse Recapitalization, each share of Old enGeneâ€™s redeemable convertible preferred stock issued and outstanding immediately prior to the close was exchanged for common shares of the Company using the Company Exchange Ratio of approximately 0.18048. A retrospective adjustment has been applied to all periods presented to reflect the Reverse Recapitalization. See Note 3, Reverse Recapitalization for additional discussion.Undesignated Preferred StockThe Companyâ€™s Certificate of Incorporation, as amended and restated, authorizes the Company to issue an unlimited number of preferred shares with no par value. The shares of preferred stock are currently undesignated. 12. Common SharesThe Company has an unlimited number of authorized shares of Common Shares, with no par value. As of October 31, 2024 and 2023 there were 50,976,676 and 23,197,976 common shares outstanding, respectively.The holders of the Common Shares are entitled to one vote for each Common Share held on all matters submitted to a vote of shareholders. Common shareholders are entitled to receive dividends, as may be declared by the Board of Directors, if any, subject to the preferential dividend rights of preferred stock. Through October 31, 2024, no cash dividends had been declared or paid. On February 13, 2024, the Company entered into subscription agreements (collectively, the â€œFebruary 2024 Subscription Agreementsâ€) with the investors named therein, for the private placement (the â€œFebruary 2024 PIPE Financingâ€) of 20,000,000 common shares of the Company, at a price of $10.00 per share. The aggregate gross proceeds from the February 2024 PIPE Financing was $200 million, before deducting offering expenses of $12.4 million. The February 2024 PIPE Financing closed on February 20, 2024.On October 24, 2024, the Company entered into subscription agreements (collectively, the â€œOctober 2024 Subscription Agreementsâ€) with the investors named therein, for the private placement (the â€œOctober 2024 PIPE Financingâ€) of 6,758,311 common shares of the Company, at a price of $8.90 per share. The aggregate gross proceeds from the October 2024 PIPE Financing was $60.1 million, before deducting offering expenses of $3.8 million. The October 2024 PIPE Financing closed on October 29, 2024. F-31 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Common share warrantsAs of October 31, 2024 and 2023, the Company had 8,511,968 and 10,411,641 warrants to purchase Common Shares outstanding, respectively. Of the warrants to purchase Common Shares outstanding as of October 31, 2024, 8,449,555 have the same terms as the FEAC public warrants issued in connection with FEACâ€™s IPO, and have an exercise price of $11.50, and are exercisable beginning 30 days after the completion of the Reverse Recapitalization and which will expire on October 31, 2028, or five years after the completion of the Reverse Recapitalization. Through October 31, 2024, 383,355 common shares have been issued as a result of the exercise of 1,379,391 warrants on a cashless basis and 520,282 common shares have been issued through cash exercises of warrants for proceeds totaling $6.0 million.The number of Common Shares to be issued upon the cashless exercise is equal to the quotient obtained by dividing (x) the product of the number of shares underlying the warrants, multiplied by the excess of the â€œFair Market Valueâ€ over the warrant exercise price of $11.50 by (y) the Fair Market Value. The Fair Market Value is the volume weighted average price of the shares for the ten (10) trading day period ending on the trading day prior to the date that notice of exercise is received by the Companyâ€™s Warrant Agent from the holder or its broker or intermediary. The warrants had a cashless exercise period until such time as the registration statement under the Securities Act with respect to the enGene Common Shares underlying the enGene Warrants was declared effective, which occurred on March 5, 2024. The Company may elect to call in the warrants for redemption if the share price of the Company equals or exceeds $18.00 for any twenty (20) trading days within the thirty (30) trading-day period ending on the third (3rd) trading day prior to the date on which notice of the redemption is given, subject to adjustments as provided in the terms of the warrant agreement.The common share warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Companyâ€™s common shares as prescribed by ASC 815.As described in Note 9, Notes Payable, the additional 62,413 of the warrants to purchase Common Shares outstanding as of October 31, 2024, were issued as part of the Amended Term Loan on December 22, 2023, have an exercise price of $7.21, and are exercisable at any time beginning on December 22, 2023 expiring on December 22, 2030, or seven years from the issuance date. The common share warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Companyâ€™s common shares as prescribed by ASC 815. As of October 31, 2024, and 2023, the Company has reserved the following Common Shares for the exercise of Common Share warrants, share options, and remaining shares reserved for future issuance under the Company's 2023 Plan (as defined below):Â Â October 31, Â Â October 31, Â Â 2024 Â Â 2023 Â Warrants to purchase common shares Â Â 8,511,968 Â Â Â 10,411,641 Â Options to purchase common shares Â Â 6,034,512 Â Â Â 2,706,941 Â Remaining shares reserved for future issuance underÂ Â Â the equity plans Â Â 2,752,889 Â Â Â 2,607,943 Â Total Â Â 17,299,369 Â Â Â 15,726,525 Â Â 13. Share-Based Compensation Pursuant to the terms of the Reverse Recapitalization, upon the Closing Date, each outstanding option to purchase Old enGeneâ€™s common stock issued under the Old Planâ€™s was exchanged for an option to purchase common shares of the Company, and the number of shares and exercise price of each granted option was adjusted using the exchange ratio of approximately 0.18048. Further, the currency of all exercise prices of the options issued under the Old Plans were converted from CAD to USD using the exchange rate in effect on the day immediately prior to the Closing Date. A retrospective adjustment has been applied to the number of options and exercise price of stock options for all periods presented to reflect the Reverse Recapitalization as discussed further in Note 3.The Old Plans Old enGene had an employee share option plan (the â€œESOPâ€) and an equity incentive plan (the â€œEIPâ€) (collectively, the â€œ Old Plansâ€) which was adopted by the Board of Directors, and approved by the shareholders, effective July 5, 2018. F-32 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â Under the Old Plans, options to purchase non-voting common shares of Old enGeneâ€™s shares may be granted to directors, officers, employees, consultants and members of the scientific advisory board. The Old Plans provide for the issuance of common stock options up to a maximum of 15% of the aggregate issued and outstanding common shares and non-voting common shares of Old enGene calculated on an as converted and fully diluted basis. The Old Plans were administered by Old enGeneâ€™s Board of Directors. Old enGeneâ€™s Board of Directors determined the number of options to be granted, the vesting period and the exercise price of new options. It was Old enGeneâ€™s policy to establish the exercise price at an amount that approximates the fair value of the underlying shares on the date of grant as determined by Old enGeneâ€™s Board of Directors. The options vest in accordance with the vesting terms determined for each grant by Old enGeneâ€™s Board of Directors. The vesting terms of Old enGeneâ€™s granted stock options with service only conditions are typically 100% vesting immediately upon grant date, or over a three- or four-year service period. Upon the consummation of the Reverse Recapitalization, the Company recognized share-based compensation expense of $0.4 million associated with the acceleration of the vesting for the outstanding awards with service only vesting conditions under the Old Plan. As of October 31, 2024 and 2023, no unrecognized compensation cost remains for the outstanding awards granted under the Old Plan with service only vesting conditions. On July 7, 2023, the Board of Directors approved the reservation of an additional 1,046,764 non-voting common shares for issuance under the Companyâ€™s employee equity incentive plan, revising the number of shares reserved from 1,775,729 to 2,822,493. Also on July 7, 2023, the Company granted 1,046,764 options to employees at an exercise price of $5.87 CAD ($4.24 USD). These options are not exercisable unless and until the completion of the Reverse Recapitalization and there is an effective registration statement for the shares underlying such granted options and will terminate automatically in the event of the termination of the Merger Agreement. The Company has valued these awards at the grant date using Black-Scholes pricing model in which the fair value of the stock on the grant date was equal to the exercise price of the award. The expected term has been determined using managementâ€™s best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, if any, and comparison to expected terms used by peers. Upon the grant date, 794,643 of the issued options were fully vested, and the remaining 252,121 options will vest over varying terms up to four years on a pro rata basis. The Company recognizes compensation expense when achievement of the performance condition is deemed probable using an accelerated attribution method, as if each vesting tranche was treated as an individual award. During the year ended October 31, 2023, $2.6 million of stock based compensation expense was recorded associated with the 1,046,764 stock options granted in July 2023 because the Reverse Recapitalization was completed and the Company determined that the filing of the registration statement was probable to occur. Upon the consummation of the Reverse Recapitalization on October 31, 2023, all options outstanding under the Old Plans were exchanged for 2,706,941 shares options to purchase common shares of the Company based on the Exchange Ratio determined in accordance with the terms of the Merger Agreement. Further, all exercise prices were adjusted by the Exchange Ratio and the currency of the exercise prices was changed from CAD to USD based on the exchange rate in effect on October 30, 2023, the day immediately before the consummation of the Reverse Recapitalization. No incremental compensation cost was recorded as a result of the change in underlying common shares from Old enGene to the Company, or as a result of the change of the exercise prices to reflect the adjustment for the Exchange Ratio and the change in currency from CAD to USD, as it was concluded that the fair value of the awards immediately before and immediately after the modifications did not change. No options remain available for grant under the Old Plans as of October 31, 2023.The 2023 PlanOn October 31, 2023, upon the completion of the Reverse Recapitalization, the shareholders approved and the Company adopted the enGene Holdings Inc. 2023 Incentive Equity Plan (the â€œ2023 Planâ€), which superseded the Old Plans. The 2023 Plan authorizes the award of incentive stock options, or ISOs, non-qualified stock options, or NQSOs, Stock Units, Stock Appreciation Rights, or SARs, and other share-based awards including performance awards and share bonus awards.The number of shares initially reserved for issuance under the 2023 Plan is 2,607,943 Common Shares, plus 2,706,941 common shares subject to the outstanding grants under the Old Plans, and shall automatically increase on January 1 of each calendar year beginning in 2024 by a number of shares equal to the lesser of 1,946,226 Common Shares and such lesser number as may be determined by the Board. The Common Shares authorized under the 2023 Plan increased by 1,946,226 on January 2, 2024. As of October 31, 2024, the total number of Common Shares reserved for issuance under the 2023 Plan is 7,261,110, and there are 2,752,889 shares remaining for issuance.The 2023 Plan is administered by the Board or, at the discretion of the Board, by a committee of the Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the Common Shares on the date of grant and the F-33 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â term of stock option may not be greater than ten years. Common Shares that are expired terminated, surrendered or cancelled under the 2023 Plan without having been fully exercised will be available for future awards.On May 15, 2024, the shareholders of the Company approved changes to the 2023 Plan. The original 2023 Plan contained an evergreen provision (the â€œEvergreen Provisionâ€) pursuant to which, commencing with the first business day of each calendar year beginning in 2024, the aggregate number of the Companyâ€™s Common Shares that could be issued or transferred thereunder (the â€œPlan Share Reserveâ€) and the number of Common Shares available for options intended to qualify as incentive stock options (the â€œISO Sublimitâ€) each increased by a number of Common Shares equal to the lesser of (x) 1,946,226 Common Shares and (y) such lesser number of Common Shares as may be determined by the Compensation Committee. Pursuant to the Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan, on May 15, 2024, the Evergreen Provision was amended to provide for annual increases on the first business day of each calendar year of (i) the Plan Share Reserve by such number of Common Shares as equals 5% of the aggregate number of Common Shares outstanding on the final day of the immediately preceding calendar year (or such smaller number of shares as is determined by the compensation committee), and (ii) the ISO Sublimit by the lesser of 2,500,000 Common Shares and the increase in the Plan Share Reserve (or such smaller number of shares may be determined by the compensation committee of the Companyâ€™s board of directors).Inducement Grants Â Pursuant to the Nasdaq inducement grant exception, during the year ended October 31, 2024, the Company issued options to purchase an aggregate of 1,643,000 Common Shares to certain new hire employees at a weighted-average exercise price of $8.69 per share. These options were granted outside of the Company's 2023 Plan. The options awarded have an exercise price equal to the closing stock price of the Company on the date of the grant and vest over four years, with 25% of the underlying shares vesting on the one-year anniversary of the grant date and the remainder vesting in equal amounts monthly for three years thereafter, subject continued service as an employee. The options have a term of 10 years from the date of the grant. As of October 31, 2024, none of the awards granted under the Inducement Grants have vested, expired, or been forfeited, and all options remain outstanding. Stock Options The assumptions that the Company used to determine the grant-date fair value of stock options during the years ended October 31, 2024 and 2023, were as follows:Â Year ended October 31, Â 2024 Â Â 2023 Â Expected term (in years) Â 5.51-6.08 Â Â 5.2Â â€“ 6.08 Â Expected volatility Â 78.24-82.33% Â Â 79.92Â â€“ 81.48% Â Risk-free interest rate Â 1.78-4.66% Â Â 3.56Â â€“ 4.35% Â Expected dividend yield Â Â â€” Â Â Â â€” Â Fair value of common shares and exerciseÂ Â Â price of options (CAD) $ N/A Â $ 2.11Â â€“ 12.36 Â Fair value of common shares and exerciseÂ Â Â price of options (USD) $ 4.73-12.60 Â $ 1.52Â â€“ 8.93 Â Â F-34 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â The following table summarizes the Companyâ€™s stock option activity: Â Â Number ofShares Â Â Weighted-AverageExercisePrice (USD) Â Â Weighted-AverageRemainingContractualTerm (in years) Â Â AggregateIntrinsicValue Â Outstanding as of October 31, 2023 Â Â 2,706,941 Â Â $ 2.40 Â Â Â 8.1 Â Â $ 52,192 Â Granted Â Â 3,591,200 Â Â Â 10.18 Â Â Â Â Â Â Â Exercised Â Â (116,752) Â Â 0.97 Â Â Â Â Â Â Â Forfeited or expired Â Â (146,877) Â Â 6.71 Â Â Â Â Â Â Â Outstanding as of October 31, 2024 Â Â 6,034,512 Â Â $ 6.88 Â Â Â 7.4 Â Â $ 17,809 Â Options vested and exercisable as of October 31, 2024 Â Â 2,497,082 Â Â $ 2.32 Â Â Â 4.4 Â Â $ 16,311 Â Options unvested as of October 31, 2024 Â Â 3,537,430 Â Â $ 10.10 Â Â Â 9.6 Â Â $ 1,498 Â Â The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Companyâ€™s common share as of each reporting period.The weighted-average grant-date fair value per share of share options granted during the years ended October 31, 2024 and 2023 was $7.30 and $2.96, respectively. Modification of Employment AgreementsOn February 13, 2024, the Company entered into a Transition and Modified Employment Agreement (the â€œTransition Agreementâ€) with the Company's former Chief Executive Officer, Jason Hanson, which amends and modifies the CEO's Employment Agreement dated November 8, 2023 (the â€œAmended Employment Agreementâ€). Under the terms of the Amended Employment Agreement Mr. Hanson will be entitled to:(i)twelve months of continued health insurance benefits; (ii)payment of a 2024 target annual bonus in the amount of $390,000, less applicable taxes and withholdings; (iii)acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination; and (iv)extension of the period to exercise his vested equity awards to three years following the later of date of termination of his employment or the date of termination of the Consulting Period (as defined below), but in no event shall the post-termination exercise period of the CEOâ€™s vested equity awards extend beyond the respective applicable term thereof.The

Transition Agreement further provided that, in the e2,vent Mr. Hanson were to resign upon the appointment by the Company of a new chief executive officer, Mr. Hanson would be immediately engaged in a consulting role to provide transition services as a Senior Strategic Advisor to the Company for a period of at least six months following the effective date of resignation (the â€œConsulting Periodâ€) in exchange for a monthly fee of $25,000 for the initial six-month Consulting Period, and $500 per hour thereafter, provided that Mr. Hanson need not devote more than fifteen (15) hours per week to providing such transition services.Under the Transition Agreement, the 1,216,266 stock option awards issued to Mr. Hanson were modified to allow for an extended exercise period as described above. The modification resulted in an incremental share-based compensation expense of $1.0 million which was recorded upon the effective date of the Transition Agreement. Mr. Hanson resigned effective as of July 19, 2024 in connection with the Companyâ€™s appointment of a new chief executive officer. On July 20, 2024, enGene appointed Ronald H. W. Cooper as Chief Executive Officer of the Company and as director of the Company's Board of Directors.Additionally, in 2024, the Company entered into a Severance Agreement with each of three former employees, including the former Chief Medical Officer and the former Chief Scientific Officer. Under the terms of Severance Agreement, the employees are entitled to twelve months of continued pay and health insurance benefits; a payment of a 2024 target annual bonus prorated through the last day of employment, acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination and an extended expiry period, which resulted in a stock-based compensation modification. Under the terms of the agreements, 231,684 stock option awards were modified to allow for an extended exercise period as described F-35 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â above. As of October 31, 2024, the Company recognized incremental stock-based compensation expense of $0.3 million related to the severance agreements.Share-based Compensation ExpenseShare-based compensation expense included in the Companyâ€™s consolidated statements of operations and comprehensive loss was as follows:Â Â Year Ended October 31, Â Â 2024 Â Â 2023 Â Research and development Â $ 1,794 Â Â $ 780 Â General and administrative Â Â 3,530 Â Â Â 2,670 Â Total share-based compensation expense Â $ 5,324 Â Â $ 3,450 Â Â As of October 31, 2024, there was $22.1 million of unrecognized compensation, which is expected to be recognized over a weighted-average period of 3.47 years. 14. Net Loss Per ShareThe following table sets forth the computation of the Companyâ€™s basic and diluted net loss per share for the periods presented, retrospectively restated to reflect the exchange of shares upon the close of the Reverse Recapitalization: Â Â Year Ended October 31, Â Â 2024 Â Â 2023 Â Numerator: Â Â Â Â Â Â Net loss Â $ 55,142 Â Â $ 99,917 Â Deemed dividend attributable to redeemable convertibleÂ Â Â preferred shareholders Â Â â€” Â Â Â 4,822 Â Net loss attributable to common shareholders, basic andÂ Â Â diluted Â $ 55,142 Â Â $ 104,739 Â Denominator: Â Â Â Â Â Â Weighted-average number of common shares used in netÂ Â Â loss per share, basic and diluted Â Â 37,782,346 Â Â Â 692,609 Â Net loss per common share, basic and diluted Â $ 1.46 Â Â $ 151.22 Â Â The Company excluded the following shares from the computation of diluted net loss per share attributable to common shareholders during the year ended October 31, 2024, and 2023 because including them would have had an anti-dilutive effect:Â Â Year Ended October 31, Â Â 2024 Â Â 2023 Â Warrants to purchase common shares Â Â 8,511,968 Â Â Â 10,411,641 Â Options to purchase common shares Â Â 6,034,512 Â Â Â 2,706,941 Â Total Â Â 14,546,480 Â Â Â 13,118,582 Â Â 15. Income TaxesLoss before provision for income taxes consisted of the following:Â Â Year ended October 31, Â Â 2024 Â Â 2023 Â Domestic (Canada) Â $ (53,460) Â $ (99,157) Foreign (US) Â Â (1,701) Â Â (743) Loss before income taxes Â $ (55,161) Â $ (99,900) Â F-36 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â The components of the provision for (recovery of) income taxes is as follows:Â Â Year ended October 31, Â Â 2024 Â Â 2023 Â Current expense (benefit): Â Â Â Â Â Â Domestic (Canada) Â $ â€” Â Â $ â€” Â Foreign (US) Â Â (19) Â Â 17 Â Total current expense (benefit) Â Â (19) Â Â 17 Â Â Â Â Â Â Â Â Deferred expense (benefit) Â Â Â Â Â Â Domestic (Canada) Â Â â€” Â Â Â â€” Â Foreign (US) Â Â â€” Â Â Â â€” Â Total deferred tax expense (benefit) Â Â â€” Â Â Â â€” Â Â Â Â Â Â Â Â Total income tax expense (benefit) Â $ (19) Â $ 17 Â Â A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:Â Â Year ended October 31, Â Â 2024 Â Â 2023 Â Income at Canadian statutory rate Â Â 26.50 % Â Â 26.50 % Conversion of debentures Â Â â€” Â Â Â (21.90)% State taxes, net of federal benefit Â Â 0.18 % Â Â 0.05 % Permanent differences Â Â (2.77)% Â Â 1.68 % Tax credits Â Â 1.07 % Â Â 0.19 % Foreign rate differential Â Â (0.17)% Â Â (0.04)% Valuation allowance Â Â (25.02)% Â Â (6.52)% Other Â Â 0.24 % Â Â 0.03 % Â Â 0.03 % Â Â (0.01)% Â The net deferred income tax balances related to the following:Â Â Â October 31, Â Â Â 2024 Â Â 2023 Â Deferred tax assets: Â Â Â Â Â Â R&D expenditures Â Â 8,172 Â Â Â 7,012 Â Net operating loss (NOL) carryforwards Â Â 31,661 Â Â Â 18,918 Â Capital loss carryforwards Â Â 97 Â Â Â â€” Â Investment tax credits, net Â Â 1,934 Â Â Â 1,210 Â Property and equipment Â Â 704 Â Â Â 791 Â Financing costs Â Â 5,452 Â Â Â 2,440 Â Accruals Â Â 747 Â Â Â 149 Â Section 174 capitalized R&D costs Â Â â€” Â Â Â 393 Â Operating lease liability Â Â 404 Â Â Â â€” Â Note payable Â Â 197 Â Â Â â€” Â Other Â Â 1 Â Â Â 172 Â Total deferred tax assets Â Â 49,369 Â Â Â 31,085 Â Deferred tax liabilities: Â Â Â Â Â Â Operating lease-right of use asset Â Â (377) Â Â â€” Â Total deferred tax liabilities Â Â (377) Â Â â€” Â Valuation allowance Â Â (48,992) Â Â (31,085) Net deferred tax assets (liability) Â Â â€” Â Â Â â€” Â Â Â Â Â Â Â Â Â F-37 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â The calculation of the Companyâ€™s tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the provinces and states in which the Company operates or does business in. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.The Company records uncertain tax positions as liabilities in accordance with ASC 740 and adjusts these liabilities when the Companyâ€™s judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of October 31, 2024 and 2023, no uncertain tax positions have been recorded in the consolidated financial statements.The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations and comprehensive loss. As of October 31, 2024 and 2023, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.As of October 31, 2024, the Company has Canadian Federal NOL carryforwards of $119.1 million, that expire between 2026 and 2044 and Canadian provincial NOL carryforwards of $113.1 million, that expire between 2029 and 2044. These losses are available to offset future taxable income in Canada and Quebec. As of October 31, 2024, the Company has a U.S. Federal NOL carryforward of $1.9 million, that may be carried forward indefinitely, and a U.S. state NOL carryforward of $1.4 million, which are available to offset against future taxable income in the U.S and Massachusetts. The U.S. State tax loss carryforward will expire between 2041 and 2043. The Company has not recognized the tax benefit of these losses. As of October 31, 2024, the Company also has non-refundable Canadian investment tax credits of $2.6 million that expire between 2025 and 2044. These credits may be utilized to reduce Canadian federal income taxes payable. The Company has not recognized the tax benefits related to these non-refundable investment tax credits.As of October 31, 2024, the Company also has capital losses of $0.7 million which are available to be used indefinitely against future capital gains.As of October 31, 2023, the Company had SR&ED expenditures of approximately $29.6 million for Canadian federal purposes and $32.5 million for QuÃ©bec provincial purposes, which have not been deducted. These expenditures are available to reduce future taxable income and have an unlimited carryforward period. SR&ED expenditures are subject to verification by the tax authorities and, accordingly, the amounts may vary. 16. LeasesThe Companyâ€™s leases are comprised of all operating leases for office and lab space.In November 2021, the Company entered into an office and lab space lease approximating 9,360 of rentable square feet for designated office and lab spaces located at 7171 Frederick-Banting, City of Montreal, judicial district of Montreal, Province of Quebec. The lease commenced in November 2021 and had an initial term of 12 months that would have expired on October 31, 2022, and includes options to renew for consecutive twelve-month periods upon landlord consent at new lease rates. As the Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet, this was considered short-term leases, and no operating lease right of use assets and liabilities were recognized. In October 2022, the Company entered into a lease amendment to extend the lease for an additional term of six months through April 2023, with an option to extend the lease through September 2023. In April 2023, the Company extended the lease through September 2023. The lease was further extended through November 5, 2023. The amendment resulted in $0.2 million of additional lease commitments to be paid during the extended term, inclusive of the extension through November 5, 2023.On December 29, 2022, the Company signed a new lease for approximately 10,620 square feet of new laboratory and office space at 4868 Rue Levy, Montreal, QC. The term of the lease is for 10 years, beginning on the commencement date, and requires an annual initial base rent of $36.50 CAD per square foot, which is subject to annual increases of 2%. The lease did not commence as of October 31, 2023 as the Company did not have access to the space as of that date. The lease commenced in November 2023. F-38 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â On January 1, 2024, the Company entered into a lease agreement, in which the Company is leasing approximately 6,450 square feet of office space located at 200 Fifth Avenue, Waltham, Massachusetts 02451. The Company will make an aggregate amount of base rental payments of $0.5 million under the initial term of the lease, which is set to expire on December 30, 2026 and does not have an option to renew. Upon commencement, the Company recognized an initial lease liability and corresponding right of use asset of $0.4 million.During the year ended October 31, 2024 and 2023, the components of operating lease cost were as follows, and are reflected in general and administrative expenses and research and development expenses, as determined by the underlying activities:Â Â Year Ended October 31, Â Â 2024 Â Â 2023 Â Lease Cost: Â Â Â Â Â Â Operating lease cost Â Â 444 Â Â Â â€” Â Variable operating lease cost Â Â 24 Â Â Â 62 Â Short-term operating lease cost Â Â â€” Â Â Â 411 Â Total operating lease cost Â Â 468 Â Â Â 473 Â Â The following table summarizes the cash paid for amounts included in the measurement of the Companyâ€™s operating lease liabilities for the year ended October 31, 2024, and 2023:Â Â Year Ended October 31, Â Â 2024 Â Â 2023 Â Cash paid for amounts included in the measurementÂ Â Â of operating lease liabilities Â $ 365 Â Â $ â€” Â Â Maturities of the Company's operating lease liabilities as of October 31, 2024 are as follows:Â 2025 Â Â 452 Â 2026 Â Â 464 Â 2027 Â Â 323 Â 2028 Â Â 299 Â 2029 Â Â 305 Â Thereafter Â Â 1,395 Â Total Â Â 3,238 Â Less: Interest Â Â (1,388) Total lease liability Â Â 1,850 Â Â As of October 31, 2024, the Company had operating lease liabilities of $1.8 million recorded on the balance sheet. As of October 31, 2023, there were no operating lease liabilities recorded on the balance sheet. 17. Commitments and Contingencies Legal Proceedings From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of October 31, 2024 and 2023, there were no matters which would have a material impact on the Companyâ€™s financial results. Purchase and Other Obligations The Company enters into contracts in the normal course of business with CROs, CDMOs and other third-party vendors for nonclinical research studies and testing, clinical trials and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including those incurred by subcontractors of our suppliers. F-39 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â 18. Related Party TransactionsDuring the year ended October 31, 2024 and 2023, the Company had the following transactions with shareholders that hold more than 10% of the total outstanding shares of the Company:On February 20, 2024, the Company completed the February 2024 PIPE Financing, which provided for the private placement of 20,000,000 Common Shares, at a price of $10.00 per share and included both new and existing investors. One of the Companyâ€™s directors, Mr. Gerald Brunk, is a managing director of Lumira Ventures (â€œLumiraâ€), and certain entities affiliated with Lumira were party to the 2024 Subscription Agreements, purchasing an aggregate of 800,000 Common Shares for a total price of $8.0 million in the February 2024 PIPE Financing. On October 29, 2024, the Company completed the October 2024 PIPE Financing, which provided for the private placement of 6,758,311 Common Shares at a price of $8.90 per share and included both new and existing investors. Two of the Companyâ€™s directors, Messrs. Jasper Bos and Wouter Joustra, are general partners of FEAC, and an entity affiliated with FEAC was party to one of the October 2024 Subscription Agreements, purchasing an aggregate of 561,797 Common Shares for a total price of approximately $5.0 million in the October 2024 PIPE Financing. On April 4, 2023, the Company entered into the April 2023 Notes for a principal amount of $8.0 million with the April 2023 investors, as described in Note 8. The April 2023 Notes had an interest free period of 45 days from the date of issuance, and commencing on the 46th day, is to accrue interest at a rate of 15% per annum. The April 2023 Notes had a maturity date which was the earlier of (i) July 31, 2023; or (ii) the date the Company completes a qualified financing, as defined within the April 2023 Notes as a financing pursuant to which the Company sells convertible promissory notes, warrants, preferred shares, common shares, or a combination thereof of the Company for an aggregate amount of at least $20.0 million. Upon the completion of the 2023 Financing, which met the definition of a qualified financing as defined within the April 2023 Notes, the Company issued and aggregate amount of $8.0 million of convertible debentures and warrants of the Company to the April 2023 Note investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing, for the extinguishment and settlement of the April 2023 Notes. On May 16, 2023, concurrently with the execution and delivery of the Merger Agreement, the Company entered into agreements pursuant to which it issued new convertible indebtedness and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in settlement and extinguishment of the April 2023 Notes for an aggregate amount of $8.0 million, as described in Note 9, Notes Payable. The 2023 Financing occurred in two separate issuances with $28.0 million issued in May 2023 for $20.0 million in cash and $8.0 million in repayment of the April 2023 Notes, and an additional $10.0 million issued in June 2023 for $10.0 million in cash. The 2023 Notes issued as part of the 2023 Financing have an initial maturity date of three years from the closing date and are to accrue interest at 10% per annum, which is payable upon maturity. The 2023 Notes have the same conversion terms as the 2022 Notes (as described in Note 9, Notes Payable). Of the $38.0 million of convertible debentures and warrants issued, $8.0 million was issued to existing shareholders of the Company, $20.0 million was issued to Forbion Growth Sponsor FEAC I B.V., and $10 million which was issued to Investissement QuÃ©bec. On October 31, 2023, upon the consummation of the Reverse Recapitalization, all of the Old enGeneâ€™s redeemable convertible preferred shares outstanding immediately prior to the close were exchanged for shares of the Companyâ€™s common shares, with no dividends or distributions being declared or paid on Old enGeneâ€™s redeemable convertible preferred shares. Further, certain of Old enGeneâ€™s existing convertible notes were converted into common shares of Old enGene at the conversion ratio in place at the time of conversion, and all of Old enGeneâ€™s common shares were exchanged for common shares of Company at the Exchange Ratio of approximately 0.18048. A total of 13,091,608 common shares of the Company were issued to the Old enGeneâ€™s equity and convertible note holders upon the close of the Reverse Recapitalization, of which 2,262,351 were issued to Forbion Growth Sponsor FEAC I B.V, as a result of itsâ€™ participation in the 2023 Financing. Each of Old enGeneâ€™s outstanding warrants to purchase common shares were exchanged for 2,679,432 common share warrants upon the close of the Reverse Recapitalization of which 950,153 were issued to Forbion Growth Sponsor FEAC I B.V, as a result of itsâ€™ participation in the 2023 Financing. All of Old enGeneâ€™s existing outstanding Class C Warrants outstanding at the time of the Reverse Recapitalization were terminated. Additionally, there were 3,670,927 common shares of the Company issued to FEAC and its shareholders, as part of the Reverse Recapitalization, along with 5,029,444 warrants to purchase common shares. Â F-40 ENGENE HOLDINGS INC.NOTES TO THE FINANCIAL STATEMENTS(AMOUNTS IN THOUSANDS OF USD, EXCEPT FOR SHARE AND PER SHARE DATA)Â 19. Subsequent EventsOn December 18, 2024 the Company entered into the First Amendment to Amended and Restated Loan and Security Agreement with Hercules (the â€œFirst Amendmentâ€), which amended the Amended Loan Agreement dated December 22, 2023. Pursuant to the First Amendment, the $7.5 million advance originally available upon achievement of the Interim Milestone (defined above) was added to the uncommitted tranche subject to the Lendersâ€™ investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time that the Lenders make additional term loan advances to the Company in an aggregate principal amount of up to $27.5 million. The Amended Term Loan Agreement did not change the total term loan facility available to the Company of up to $50.0 million. The Company has evaluated subsequent events through the date these financial statements were issued. The Company concluded that no additional subsequent events have occurred that require disclosure. F-41 EX-10.32 2 engn-ex10_32.htm EX-10.32 EX-10.32 Â Exhibit 10.32 Â AMENDED & RESTATED EMPLOYMENT AGREEMENT FOR ANTHONY CHEUNG Â THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT (the â€œAgreementâ€) is entered into as of October 16, 2024, by and between enGene Inc. (the â€œCompanyâ€) and Anthony Cheung (the â€œExecutiveâ€). Â WHEREAS, the Company and the Executive previously entered into an Employment Agreement dated November 8, 2023 (â€œNovember 8, 2023 Agreementâ€); Â WHEREAS, the Company has determined that it is in the best interest of the Company to continue the services and employment of the Executive as its Chief Scientific Officer, and the Executive is willing to render such services on the terms and conditions set forth herein; and Â WHEREAS, the parties desire to amend and restate the November 8, 2023 Agreement to reflect such terms and conditions as set forth herein this Agreement. Â NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, the Company and the Executive hereby agree as follows: 1.Employment. (a)Term. This Agreement shall begin on October 21, 2024 (the â€œEffective Dateâ€) and shall continue for an indeterminate term until the termination of the Executiveâ€™s employment in accordance with this Agreement. The period commencing on the Effective Date and ending on the date on which the term of this Agreement terminates is referred to herein as the â€œTermâ€. (b)Duties. During the Term, the Executive shall serve as the Chief Scientific Officer with such duties, responsibilities, and authority commensurate therewith, and shall report to the Chief Executive Officer of the Company (the â€œCEOâ€). The Executive shall perform all duties and accept all responsibilities incident to such position as may be reasonably assigned to the Executive by the CEO. (c)Best Efforts. During the Term, the Executive shall devote the Executiveâ€™s best efforts and full time and attention to promote the business and affairs of the Company and its affiliated entities, and shall be engaged in other business activities only to the extent that such activities do not materially interfere or conflict with the Executiveâ€™s obligations to the Company hereunder, including, without limitation, obligations pursuant to Section 14 below. The foregoing shall not be construed as preventing the Executive from (i) serving on civic, educational, philanthropic or charitable boards or committees, or, with the prior written consent of the CEO, in his sole discretion, on corporate boards, and (ii) managing personal investments, so long as such activities are permitted under the Companyâ€™s Code of Conduct and employment policies and do not violate the provisions of Section 14 below. (d)Principal Place of Employment. The Executive understands and agrees that the Executiveâ€™s principal place of employment will continue to be in the Companyâ€™s offices located in the greater Montreal area in the province of Quebec and that the Executive will be required to travel for business in the course of performing the Executiveâ€™s duties for the Company. Â Â Â Â 2.Compensation. (a)Base Salary. During the Term, the Company shall pay the Executive a base salary (â€œBase Salaryâ€), at the annual rate of USD $450,000.00 (FOUR HUNDRED AND FIFTY THOUSAND DOLLARS), which shall be paid in installments in accordance with the Companyâ€™s normal payroll practices. The Executiveâ€™s Base Salary shall be reviewed annually by the Compensation Committee (the â€œCompensation Committeeâ€) of the Board of Directors (the â€œParent Boardâ€) of enGene Holdings Inc. (â€œParentâ€). (b)Annual Bonus. The Executive shall be eligible to receive an annual bonus for each fiscal year during the Term, commencing with the 2024 calendar year, based on the attainment of individual and corporate performance goals and targets established by the Compensation Committee (â€œAnnual Bonusâ€). The target amount of the Executiveâ€™s Annual Bonus for any fiscal year during the Term is 40% of the Executiveâ€™s annual Base Salary (the â€œTarget Annual Bonusâ€). Any Annual Bonus shall be paid after the end of the calendar year to which it relates, at the same time and under the same terms and conditions as the bonuses are paid to other executives of the Company; provided, that, in no event shall the Executiveâ€™s Annual Bonus be paid later than two and a half months after the last day of the calendar year to which the Annual Bonus relates. (c)Equity Compensation. The Executive shall be eligible to participate in the enGene Holdings Inc. 2023 Incentive Equity Plan (the â€œEquity Planâ€) at a level commensurate with similar to similarly situated executives of the Company, as determined in the sole discretion of the Compensation Committee. For 2024, subject to the Equity Plan and the terms of the Companyâ€™s equity compensation program for 2024, the Executiveâ€™s annual equity target amount shall be based on the mid-point range of the benchmarking analysis prepared by the Companyâ€™s independent compensation consultant, currently Pay Governance. 3.Retirement and Welfare Benefits. During the Term, the Executive shall be eligible to participate in the Companyâ€™s health, life insurance, long-term disability, retirement and welfare benefit plans and programs, pursuant to their respective terms and conditions. Nothing in this Agreement shall preclude the Company or any Affiliate of the Company from terminating or amending any employee benefit plan or program from time to time after the Effective Date. The Company shall also reimburse the Executive for access to private health clinics for him and his spouse (Telus Health Centres). 4.Vacation. During the Term, the Executive shall be entitled to 25 (TWENTY-FIVE) days of paid annual vacation each year (which shall accrue at the rate of 2.08 days per calendar month); holiday and sick leave shall be at levels commensurate with those provided to similarly situated executives of the Company, in accordance with the Companyâ€™s policy and/or practices. If, at the end of the vacation year applicable to the Executive, he has unused vacation time, it shall be paid-out to him. 5.Business Expenses. The Company shall reimburse the Executive for all necessary and reasonable travel (which does not include commuting) and other business expenses incurred by the Executive in the performance of his duties hereunder in accordance with such policies and procedures as the Company may adopt generally from time to time for executives. 2Â Â 6.Termination of Employment Without Serious Reason; Resignation for Good Reason. If the Executiveâ€™s employment is terminated by the Company without Serious Reason or by the Executive for Good Reason, the provisions of this Section 6 shall apply. (a)The Company may terminate the Executiveâ€™s employment with the Company at any time without Serious Reason by notifying the Executive in writing thereof and the Executive may resign for Good Reason. (b)Unless the Executive complies with the provisions of Section 6(c) below, upon termination of employment under Section 6(a) above, no other payments or benefits shall be due under this Agreement to the Executive other than the Accrued Obligations. (c)Notwithstanding the provisions of Section 6(b) above, upon termination of employment under Section 6(a) above, if the Executive executes the Release, and so long as the Executive continues to comply with the provisions of Section 14 below, in addition to the Accrued Obligations, the Executive shall be entitled to receive the following: (i)As payment of an indemnity in lieu of prior reasonable notice of termination, the continuation of the Executiveâ€™s Base Salary for the 18-month (EIGHTEEN MONTH) period (the â€œIndemnity Termâ€), at the rate in effect for the year in which the Executiveâ€™s date of termination of employment occurs, which amount shall be paid in regular payroll installments over the Indemnity Term; and (ii)Continued health (including hospitalization, medical, dental, vision etc.) insurance coverage substantially similar in all material respects as the coverage provided to other Company employees for the Indemnity Term; provided that the Executive shall pay the employee portion of such coverage, the period health care continuation coverage shall run concurrently with the Indemnity Term, and notwithstanding the foregoing, the amount of any benefits provided by this subsection (ii) shall be eliminated to the extent the Executive becomes entitled to duplicative benefits by virtue of the Executiveâ€™s subsequent or other employment. (iii)An amount equal to the Target Annual Bonus, prorated for the portion of the performance period that the Executive was employed prior to such termination, payable within forty-five (45) days of Executiveâ€™s termination of employment; provided, that such termination occurs six months or more into the applicable performance period for such Annual Bonus. (iv)Any time-based equity awards shall accelerate and vest with respect to the number of shares underlying the equity awards that would vest over the Indemnity Term had the Executive remained employed for such Indemnity Term and any equity awards that are subject to performance-based vesting shall vest and become exercisable, if at all, subject to the terms of such equity awards. 7.Change in Control. Notwithstanding anything to the contrary herein, if there is a CIC Termination, then the provisions of this Section 7 shall apply. (a)Unless the Executive complies with the provisions of Section 7(b) below, upon CIC Termination, no other payments or benefits shall be due under this Agreement to the Executive other than the Accrued Obligations. 3Â Â (b)Notwithstanding the provisions of Section 7(a) above, upon CIC Termination, if the Executive executes the Release, and so long as the Executive continues to comply with the provisions of Section 14 below, then, in addition to the Accrued Obligations, the Executive shall be entitled to receive the following as compensation and benefits in lieu of prior reasonable notice of termination of employment: (i)Continuation of the Executiveâ€™s Base Salary for the 18-month (EIGHTEEN MONTH) period (the â€œCIC Indemnity Termâ€), at the rate in effect for the year in which the Executiveâ€™s date of termination of employment occurs, which amount shall be paid in regular payroll installments over the CIC Severance Term; (ii)An amount equal to the Annual Target Bonus, payable within forty-five (45) days of Executiveâ€™s termination of employment; (iii)Continuation of benefits as set forth in Section 6(c)(ii), except that the Indemnity Term shall be the CIC Indemnity Term; and (iv)All time-based equity awards shall accelerate and become fully vested and any equity awards that are subject to performance-based vesting shall vest, if at all, subject to the terms of such equity awards. 8.Serious Reason. The Company may terminate the Executiveâ€™s employment at any time for Serious Reason upon simple written notice to the Executive, in which event all payments under this Agreement shall cease, except for any Accrued Obligations. 9.Voluntary Resignation Without Good Reason. The Executive may voluntarily terminate employment without Good Reason upon 30 daysâ€™ prior written notice to the Company. In such event, after the effective date of such termination, no payments shall be due under this Agreement, except that the Executive shall be entitled to any Accrued Obligations. 10.Disability. If the Executive incurs a Disability during the Term, subject to applicable law regarding accommodating the Executiveâ€™s disability, the Company may terminate the Executiveâ€™s employment on or after the date of Disability. If the Executiveâ€™s employment terminates on account of Disability, the Executive shall be entitled to receive any Accrued Obligations and if the Executive executes the Release, an amount equal to the Target Annual Bonus, prorated for the portion of the performance period that the Executive was employed prior to such termination for Disability; provided, that such termination occurs six months or more into the applicable performance period. For purposes of this Agreement, the term â€œDisabilityâ€ shall mean the Executive is eligible to receive long-term disability benefits under the Companyâ€™s long-term disability plan and if the Company does not have a long-term disability plan, shall mean the Executiveâ€™s inability, due to physical or mental incapacity, to perform the essential functions of Executiveâ€™s position, with or without reasonable accommodation, for 120 days out of any 365 day period. 11.Death. If the Executive dies during the Term, the Executiveâ€™s employment shall terminate on the date of death and the Company shall pay to the Executiveâ€™s executor, legal representative, administrator or designated beneficiary, as applicable, any Accrued Obligations. The Company shall have no further liability or obligation under this Agreement to the Executiveâ€™s executors, 4Â Â legal representatives, administrators, heirs or assigns or any other person claiming under or through the Executive. 12.Resignation of Positions. Effective as of the date of any termination of employment, the Executive will resign from all Company-related positions, including as an officer and director of the Company and its parent(s), subsidiaries, and Affiliates. 13.Definitions. For purposes of this Agreement, the following terms shall have the following meanings: (a)â€œAccrued Obligationsâ€ shall mean (i) any Base Salary earned through the Executiveâ€™s termination of employment that remains unpaid; (ii) any Annual Bonus payable with respect to any calendar year which ended prior to the effective date of the Executiveâ€™s termination of employment, which remains unpaid; (iii) in the event of a termination of employment as a result of death, an amount equal to the Target Annual Bonus, prorated for the portion of the performance period that the Executive was employed prior to such termination; provided, that such termination occurs six months or more into the applicable performance period for such Annual Bonus; or (iv) any accrued, unused personal time off days, if required to be paid out under the Company policies. The Accrued Obligations shall be paid following the Executiveâ€™s termination of employment at such times and in accordance with such policies as would normally apply to such amounts and regardless of whether the Executive executes or revokes the Release. (b)â€œChange in Controlâ€ shall have the meaning set forth in the Equity Plan. (c)â€œChange in Control Periodâ€ shall mean the period commencing 90 days prior to a Change in Control and ending on the first anniversary of such Change in Control. (d)â€œCIC Terminationâ€ shall mean termination of the Executiveâ€™s employment by the Company without Serious Reason or by the Executive for Good Reason during the Change in Control Period, provided that, in either case, a Change in Control actually occurs. (e)â€œGood Reasonâ€ shall mean the occurrence of one or more of the following without the Executiveâ€™s consent, other than on account of the Executiveâ€™s Disability: (i) A material diminution by the Company of the Executiveâ€™s authority, reporting structure, duties or responsibilities; (ii) A material change in the geographic location at which the Executive must perform services under this Agreement (which, for purposes of this Agreement, means relocation of the offices of the Company at which the Executive is principally employed to a location that increases the Executiveâ€™s commute to work by more than 75 kilometers); (iii) A material diminution in the Executiveâ€™s Base Salary (other than an across the board reduction of base salary for similarly situated senior level employees); or (iv) Any action or inaction that constitutes a material breach by the Company of this Agreement. The Executive must provide written notice of termination for Good Reason to the Company within 60 days after the event constituting Good Reason. The Company shall have a period of 30 days in which it may correct the act or failure to act that constitutes the grounds for Good Reason as set forth in the Executiveâ€™s notice of termination. If the Company does not correct the act or failure to act, the Executiveâ€™s employment will terminate for Good Reason on the first business day following the Companyâ€™s 30-day cure period. 5Â Â (f)â€œReleaseâ€ shall mean a separation agreement and general release of any and all claims against the Company and its Affiliates with respect to all matters arising out of the Executiveâ€™s employment by the Company, and the termination thereof (other than claims for any entitlements under the terms of this Agreement or under any plans or programs of the Company under which the Executive has accrued and is due a benefit). The Release will be in form and substance specified by and acceptable to the Company and will include provisions in which the Executive shall reaffirm and agree to remain bound by the restrictive covenants set forth in Section 14 below. Such general release shall be executed and delivered by the Executive within sixty (60) days following delivery of the general release to the Executive. (g)â€œSerious Reasonâ€ shall mean any of the following grounds for the Executiveâ€™s termination of employment listed: (i) the Executiveâ€™s knowing and material dishonesty or fraud committed in connection with the Executiveâ€™s employment; (ii) theft, misappropriation, or embezzlement by the Executive of the Companyâ€™s funds; (iii) the Executive repeatedly negligently performing or failing to perform, or willfully refusing to perform, the Executiveâ€™s duties to the Company (other than a failure resulting from Executiveâ€™s incapacity due to physical or mental illness); (iv) the Executiveâ€™s conviction of or a plea of guilty to any crime involving fraud or misrepresentation, or any other crime (whether or not connected with his employment) the effect of which is likely to adversely affect the Company or its Affiliates; (v) a material breach by the Executive of any of the provisions or covenants set forth in this Agreement; (vi) a material breach by the Executive of the Companyâ€™s Code of Conduct and Business Ethics; (vii) any other act or omission by the Executive that has a material adverse effect on the Companyâ€™s ability to operate or (viii) any other acts, omissions or circumstances that constitute a serious reason for termination of employment without prior notice pursuant to Article 2094 of the Civil Code of Quebec. Prior to any termination of employment for Serious Reason pursuant to each such event listed in (i), (iii), (v), (vi), or (vii) above, to the extent such event(s) is capable of being cured by the Executive, the Company shall give the Executive written notice thereof describing in reasonable detail the circumstances constituting the Serious Reason and the Executive shall have the opportunity to remedy same within thirty (30) days after receiving written notice. 14.Restrictive Covenants. (a)Noncompetition. The Executive agrees that during the Executiveâ€™s employment with the Company and its Affiliates and for eighteen (18) months following a termination of employment for any reason, including a termination of employment where an indemnity is not payable to the Executive (the â€œRestriction Periodâ€), the Executive will not, without the Boardâ€™s express written consent, engage (directly or indirectly) in any Competitive Business in the United States or Canada. The term â€œCompetitive Businessâ€ means any person, concern or entity which is engaged in or conducts a business substantially the same as the Business of the Company and its Affiliates. The term â€œBusinessâ€ means the discovery, research, development and commercialization by the Company or its Affiliates of gene therapy treatments currently under active discovery, development or commercialization (generally referred to internally as â€œProgramsâ€ and â€œPipelineâ€), including material external sponsored research agreements. The Executive understands and agrees that, given the nature of the business of the Company and its Affiliates and the Executiveâ€™s position with the Company, the foregoing scope is reasonable and appropriate, and necessary to protect the Companyâ€™s legitimate business interests. For purposes of this Agreement, the term â€œAffiliateâ€ means any subsidiary of the Company or Parent or any 6Â Â other entity under common control with the Company. Executive and the Company agree that the terms set forth in this Agreement, including without limitation, the increase in Base Salary, the Annual Bonus opportunity and rights to an indemnity in lieu of notice or termination that the Company is awarding the Executive as consideration for the covenants in this Section 14(a) constitute mutually-agreed upon consideration for the Executiveâ€™s compliance with this Section 14(a). (b)Nonsolicitation of Company Personnel. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, attempt to hire any employee, consultant or independent contractor of the Company or its Affiliates, or solicit or attempt to solicit any such person to change or terminate his or her relationship with the Company or an Affiliate or otherwise to become an employee, consultant or independent contractor to, for or of any other person or business entity, unless more than 12 months shall have elapsed between the last day of such personâ€™s employment or service with the Company or Affiliate and the first day of such solicitation or attempt to solicit or hire; provided that the foregoing does not prohibit general solicitation or recruitment activities not directed at employees of the Company or soliciting, recruiting or hiring any person who responds thereto. (c)Nonsolicitation of Customers. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, solicit, divert or appropriate, or attempt to solicit, divert or appropriate, any customer or actively sought prospective customer of the Company or an Affiliate for the purpose of providing such customer or actively sought prospective customer with services or products competitive with those offered by the Company or an Affiliate during the Executiveâ€™s employment with the Company or an Affiliate; provided however that, for the portion of the Restriction Period occurring following the last day of the Term, this restriction shall only apply to customers or prospective customers with whom the Executive had business contact within the 12-month period immediately preceding the Executiveâ€™s last day of work. (d)Proprietary Information. At all times, the Executive will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Proprietary Information (defined below) of the Company or an Affiliate, except as such disclosure, use or publication may be required in connection with the Executiveâ€™s work for the Company, the Company expressly authorizes such disclosure in writing. â€œProprietary Informationâ€ shall mean any and all confidential and/or proprietary knowledge, data or information of the Company and its Affiliates and shareholders, including but not limited to information relating to financial matters, investments, budgets, business plans, marketing plans, personnel matters, business contacts, products, processes, know-how, designs, methods, improvements, discoveries, inventions, ideas, data, programs, and other works of authorship. For purposes of this Agreement, the term â€œProprietary Informationâ€ shall not include information which is or becomes publicly available without breach of: (i) this Agreement; (ii) any other agreement or instrument to which the Company or an Affiliate is a party or a beneficiary; or (iii) any duty owed to the Company or an Affiliate by the Executive or by any third party. It shall also not include any information that was reasonably demonstrated to be known to the Executive prior to the Executiveâ€™s employment with the Company; provided, however, that if the Executive shall desire or seek to disclose, use, lecture upon, or publish any Proprietary Information, the Executive shall first obtain approval from the Company. 7Â Â (e)Inventions Assignment. The Executive agrees that all inventions, innovations, improvements, developments, methods, designs, analyses, reports, and all similar or related information which relates to the Companyâ€™s or its Affiliatesâ€™ actual or anticipated business, research and development of existing or future products or services and which are conceived, developed or made by the Executive while employed by the Company (â€œWork Productâ€) belong to the Company. The Executive will promptly disclose such Work Product to the Board and perform all actions reasonably requested by the Board (whether during or after the Term) to establish and confirm such ownership (including, without limitation, assignments, consents, powers of attorney and other instruments). If requested by the Company, the Executive agrees to execute any inventions assignment and confidentiality agreement that is required to be signed by Company employees generally. The Executive hereby waives, to the full extent permitted by applicable law, any â€œmoral rightsâ€ in and to any Work Product. (f)Non-Disparagement. The Executive agrees and covenants that the Executive will not at any time make, publish or communicate in any public forum or otherwise in a manner intended to achieve widespread publication or broadcast outside the Company or to substantial numbers of employees of the Company, any defamatory or disparaging remarks, comments or statements concerning the Company or its businesses, or any of its employees, officers, and existing and prospective customers, suppliers, or investors. (g)Return of Company Property. Upon termination of the Executiveâ€™s employment with the Company for any reason, and at any earlier time the Company requests, the Executive will deliver to the person designated by the Company all originals and copies of all documents and property of the Company or an Affiliate that is in the Executiveâ€™s possession or under the Executiveâ€™s control or to which the Executive may have access. The Executive will not reproduce or appropriate for the Executiveâ€™s own use, or for the use of others, any property, proprietary information, or Work Product. (h)Restrictive Covenant Acknowledgement. The Executive acknowledges and agrees that the foregoing restrictions contained in Section 14 are reasonable, proper and necessitated by the legitimate business interests of the Company and will not prevent the Executive from earning a living or pursuing a career. 15.Personal Information. The Executive consents to the Company collecting, using and disclosing his personal information for purposes of administering his employment relationship or in the event of any proposed financing, sale or acquisition, provided that such disclosure is in accordance with the Companyâ€™s privacy policies and practices and applicable law. The Executive hereby acknowledges that his personal information will be held in Quebec but may be transferred and stored and/or processed in jurisdictions outside of Quebec, including the following jurisdiction(s): other Canadian provinces, United States of America and the European Union. Only individuals having a legitimate need to know the information will have access to the Employee's information: including human resources, management and finance personnel and then, only on a need-to-know basis. The Executive may access and/or request correction of his information by contacting the Company's human resources representative(s). Such requests will be processed in accordance with applicable law. 16.Legal and Equitable Remedies. Because the Executiveâ€™s services are personal and unique and the Executive has had and will continue to have access to and has become and will continue 8Â Â to become acquainted with the proprietary information of the Company and its Affiliates, and because any breach by the Executive of any of the restrictive covenants contained in Section 14 would result in irreparable injury and damage for which money damages would not provide an adequate remedy, the Company shall have the right to enforce Section 14 and any of its provisions by injunction, performance in kind or other relief or recourse, without prejudice to any other rights and remedies that the Company may have for a breach, or threatened breach, of the restrictive covenants set forth in Section 14. 17.Survival. The respective rights and obligations of the parties under this Agreement (including, but not limited to, under Section 14) shall survive any termination of the Executiveâ€™s employment or termination or expiration of this Agreement to the extent necessary to the intended preservation of such rights and obligations. 18.Notices. All notices and other communications required or permitted under this Agreement or necessary or convenient in connection herewith shall be in writing and shall be deemed to have been given when emailed, hand delivered or mailed by registered or certified mail, as follows (provided that notice of change of address shall be deemed given only when received): If to the Company, to: 4868 Rue Levy, Suite 220, Saint-Laurent, QuÃ©bec Canada H4R 2P9 Attn: Chief Executive Officer If to the Executive, to the most recent address on file with the Company or to such other names or addresses as the Company or the Executive, as the case may be, shall designate by notice to each other person entitled to receive notices in the manner specified in this Section. 19.Withholding. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, provincial and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. The Executive shall bear all expense of, and be solely responsible for, all applicable taxes due with respect to any payment received under this Agreement. 20.Remedies Cumulative; No Waiver. No remedy conferred upon a party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given under this Agreement or now or hereafter existing at law or in equity. No delay or omission by a party in exercising any right, remedy or power under this Agreement or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in its sole discretion. 21.Assignment. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective heirs, executors, administrators, legal representatives, successors and assigns of the parties hereto, except that the duties and responsibilities of the Executive under this Agreement are of a personal nature and shall not be assignable or delegable in whole or in part by the Executive. The Company may assign its rights, together with its obligations hereunder, in connection with any sale, transfer or other disposition 9Â Â of all or substantially all of its business and assets, and such rights and obligations shall inure to, and be binding upon, any successor to the business or any successor to substantially all of the assets of the Company, whether by merger, purchase of stock or assets or otherwise, which successor shall expressly assume such obligations, and the Executive acknowledges that in such event the obligations of the Executive hereunder, including but not limited to those under Section 14, will continue to apply in favor of the successor. 22.Company Policies. This Agreement and the compensation payable hereunder shall be subject to any applicable clawback or recoupment policies, share trading policies, and other policies that may be implemented by the Board from time to time with respect to officers of the Company. 23.Indemnification. In the event the Executive is made, or threatened to be made, a party to any legal action or proceeding, whether civil or criminal, including any governmental or regulatory proceedings or investigations, by reason of the fact that the Executive is or was a director or officer of the Company or any of its Affiliates, the Executive shall be indemnified by the Company, and the Company shall pay the Executiveâ€™s related expenses (including reasonable attorneysâ€™ fees, judgments, fines, settlements and other amounts incurred in connection with any proceeding arising out of) when and as incurred, to the fullest extent permitted by applicable law and the Companyâ€™s articles of incorporation and bylaws. During the Executiveâ€™s employment with the Company or any of its Affiliates and after termination of employment for any reason, the Company shall cover the Executive under the Companyâ€™s directorsâ€™ and officersâ€™ insurance policy applicable to other officers and directors according to the terms of such policy. Such obligations shall be binding upon the Companyâ€™s successors and assigns and shall inure to the benefit of the Executiveâ€™s heirs and personal representatives. 24.Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto and supersedes any and all prior agreements and understandings concerning the Executiveâ€™s employment by the Company, including without limitation that certain Employment Agreement between the Company and the Executive, made as of July 26, 2013 and the November 8, 2023 Agreement. This Agreement may be changed only by a written document signed by the Executive and the Company. 25.Severability. If any provision of this Agreement or application thereof to anyone or under any circumstances is adjudicated to be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect any other provision or application of this Agreement, which can be given effect without the invalid or unenforceable provision or application and shall not invalidate or render unenforceable such provision or application in any other jurisdiction. If any provision is held void, invalid or unenforceable with respect to particular circumstances, it shall nevertheless remain in full force and effect in all other circumstances. 26.Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with the laws of the Province of QuÃ©bec and the federal laws of Canada appliable therein. 10Â Â 27.Counterparts. This Agreement may be executed in any number of counterparts (including facsimile counterparts), each of which shall be an original, but all of which together shall constitute one instrument. 28.Acknowledgments. The Executive acknowledges that (a) the Executive has the right to consult with counsel prior to signing this Agreement and has had a full and adequate opportunity to read, understand and discuss with the Executiveâ€™s advisors, including counsel, the terms and conditions contained in this Agreement prior to signing hereunder, (b) this Agreement is supported by fair and reasonable consideration independent from the continuation of employment, and (c) the Executive received notice of this Agreement at least ten business days before it is to be effective. 29.Language. The Executive hereby confirms that he has retained legal counsel to assist him in negotiating and entering into this Agreement. Furthermore, he hereby acknowledges and agrees that he, through his legal counsel, has freely and voluntarily negotiated the essential terms and conditions thereof prior to signing of his own accord this Agreement, and, as a result, he further acknowledges and agrees that this Agreement is and must be construed as at all times and under all applicable law as a private agreement (contrat de grÃ© Ã grÃ©), and not as a contract of adhesion. Therefore, the Executive has agreed that this Agreement be drafted in English only and has thus agreed to sign it drafted as such at his request and of his own accord. Le salariÃ© confirme quâ€™il a retenu les services de conseillers juridiques afin de lâ€™assister dans le cadre de la nÃ©gociation et de la conclusion de ce Contrat. De plus, il reconnait et convient quâ€™il a, avec le concours de ses conseillers juridiques respectifs, nÃ©gociÃ© librement et volontairement les modalitÃ©s et conditions essentielles de ce Contrat avant de signer de son plein grÃ© ce Contrat, et, en consÃ©quence, il reconnait et convient Ã©galement que ce Contrat est et doit Ãªtre interprÃ©tÃ© en tout temps comme un contrat de grÃ© Ã grÃ© en vertu de toute loi applicable, et non pas comme un contrat dâ€™adhÃ©sion. DÃ¨s lors, le salariÃ© a convenu que ce Contrat ne soit rÃ©digÃ© quâ€™en anglais et il a convenu de signer ce Contrat rÃ©digÃ© ainsi Ã sa demande et de son plein grÃ©. (Signature Page Follows) 11Â Â IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written. Â ENGENE INC. Â /s/ Ronald H. W. Cooper Name: Ronald H. W. Cooper Title: Chief Executive Officer Date: 10/16/2024 Â EXECUTIVE Â /s/ Anthony Cheung Name: Anthony Cheung Date: 10/16/2024 Â Â 12Â EX-10.33 3 engn-ex10_33.htm EX-10.33 EX-10.33 Â Exhibit 10.33 EMPLOYMENT AGREEMENT FOR JOAN CONNOLLY THIS EMPLOYMENT AGREEMENT (this â€œAgreementâ€) is entered into by and between enGene USA, Inc., its successors and assigns (the â€œCompanyâ€) and Joan Connolly (the â€œExecutiveâ€) as of the date first written below. WHEREAS, the Company desires to employ the Executive to serve as the Companyâ€™s Chief Technology Officer and the Executive desires to serve in such capacity on behalf of the Company. NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, the Company and the Executive hereby agree as follows: 1.Employment. (a)Term. The initial term of this Agreement shall begin on October 21, 2024 (the â€œEffective Dateâ€) and shall continue until the termination of the Executiveâ€™s employment. The period commencing on the Effective Date and ending on the date on which the term of this Agreement terminates is referred to herein as the â€œTerm.â€ The Executiveâ€™s employment during the Term shall be as an â€œat-willâ€ employee; the Executive may resign from employment at any time, and the Company may terminate the Executiveâ€™s employment at any time, for any reason or no reason, subject to the provisions of this Agreement. (b)Duties. During the Term, the Executive shall serve as the Chief Technology Officer, with such duties, responsibilities, and authority commensurate therewith, and shall report to the Chief Executive Officer of the Company (the â€œCEOâ€). The Executive shall perform all duties and accept all responsibilities incident to such position as may be reasonably assigned to the Executive by the CEO that are consistent with and within the scope of Executiveâ€™s position. (c)Best Efforts. During the Term, the Executive shall devote the Executiveâ€™s best efforts and full business time and attention to promote the business and affairs of the Company and its affiliated entities, and shall be engaged in other business activities only to the extent that such activities do not materially interfere or conflict with the Executiveâ€™s obligations to the Company hereunder, including, without limitation, obligations pursuant to Section 15 below. The foregoing shall not be construed as preventing the Executive from (i) serving on civic, educational, philanthropic or charitable boards or committees, or, with the prior written consent of the CEO, which shall not be unreasonably withheld, on corporate, advisory or scientific advisory boards, or service in an advisory capacity to a corporate entity and (ii) managing personal investments, so long as such activities are permitted under the Companyâ€™s Code of Conduct and employment policies and do not violate the provisions of Section 15 below. (d)Principal Place of Employment. The Executive understands and agrees that the Executiveâ€™s principal place of employment will be in the Executiveâ€™s home in New Jersey and that employment will remain remote but the Executive will be required to travel the Companyâ€™s headquarters in or around Boston, Massachusetts (â€œPrincipal Place of Employmentâ€). The Executiveâ€™s employment and all services hereunder shall be provided in the United States and the Executive shall not be required to work in Canada during the Term of this Agreement. Executive will be required to travel for business in the course of performing the Executiveâ€™s duties for the Company. 1Â Â 2.Compensation. (a)Base Salary. During the Term, the Company shall pay the Executive a base salary (â€œBase Salaryâ€), at the annual rate of $440,000.00, which shall be paid in installments in accordance with the Companyâ€™s normal payroll practices. The Executiveâ€™s Base Salary shall be reviewed annually by the Compensation Committee (the â€œCompensation Committeeâ€) of the Board of Directors (the â€œParent Boardâ€) of enGene Holdings Inc. (â€œParentâ€), and may be increased, but not decreased. (b)Sign-on Bonus. The Executive will be eligible to receive a one-time sign-on bonus in the amount of $30,000, less applicable deductions and withholdings, (the â€œSign-On Bonusâ€), which will be paid to the Executive in the first regular payroll period following the Effective Date. The Sign-On Bonus will not actually be deemed earned until the Executive has completed one full year of active employment with the Company in good standing, and shall be deemed an unearned advance until this condition has been satisfied. In the event that the Executive voluntarily resign from employment with the Company for any reason within the Executiveâ€™s first year of employment, or is terminated by the Company for Cause (as defined in Section 13 below), the Executive agrees to repay to the Company the entire value of the Sign-On Bonus, with such repayment occurring within thirty (30) days following the Executiveâ€™s last day of employment with the Company. The Executive further agrees that the Company may make any deduction necessary from the Executiveâ€™s last paycheck(s) to satisfy this repayment obligation, and the Executive hereby (i) consent to any such deduction and any other action that may be taken by the Company and as permitted by law, and (ii) agrees that, at the time of such separation, the Executive will sign any additional agreement or document that the Company deems necessary with respect to making this deduction or otherwise enforcing its right to receive the repayment amount. (c)Annual Bonus. The Executive shall be eligible to receive an annual bonus for each calendar year during the Term, commencing with the 2025 calendar year, based on the attainment of individual and corporate performance goals and targets established by the Compensation Committee (â€œAnnual Bonusâ€). The target amount of the Executiveâ€™s Annual Bonus for any calendar year during the Term is 40% of the Executiveâ€™s annual Base Salary (the â€œTarget Annual Bonusâ€). Any Annual Bonus shall be paid after the end of the fiscal year to which it relates, at the same time and under the same terms and conditions as the bonuses are paid to other executives of the Company; provided, that, in no event shall the Executiveâ€™s Annual Bonus be paid later than two and a half months after the last day of the fiscal year to which the Annual Bonus relates. (d)Equity Compensation. Subject to the approval of the Parent Board, as an inducement for the Executive to join the Company in the role of Chief Technology Officer and agree to the restrictive covenants set forth below, the Executive will be granted the Option (as further described below), which is intended to be an inducement award under Rule 5635(c)(4) of the Nasdaq Stock Market Listing Rules and will be granted outside of the enGene Holdings Inc. Amended and Restated 2023 Incentive Equity Plan (the â€œEquity Planâ€). Although granted as an inducement award outside of the Plan, the Option shall be subject to the terms of the Equity Plan as if issued thereunder. (1)Stock Option. The Executive will be granted a nonqualified stock option to purchase 210,000 common shares of Company, subject to the terms of the nonqualified stock option agreement for inducement grants provided by the Company (the â€œOptionâ€). Vesting and exercisability of the Option will be over four years with 25% vesting and becoming exercisable 2Â Â on the first anniversary of the Effective Date, and the remainder vesting and becoming exercisable in substantially equal amounts monthly for three years thereafter. The exercise price of the Option will be the closing price of the Companyâ€™s common shares on the date the Option is granted. (2)Future Equity Compensation. In addition, the Executive shall be eligible to participate in the Equity Plan at a level commensurate with similarly situated C-Suite executives of the Company, as determined in the sole discretion of the Compensation Committee and/or Parent Board. 3.Retirement and Welfare Benefits. During the Term, the Executive shall be eligible to participate in the Companyâ€™s health, life insurance, long-term disability, retirement and welfare benefit plans and programs, pursuant to their respective terms and conditions. Nothing in this Agreement shall preclude the Company or any Affiliate of the Company from terminating or amending any employee benefit plan or program from time to time after the Effective Date. 4.Vacation. During the Term, the Executive shall be eligible to vacation each year and holiday and sick leave at levels commensurate with those provided to similarly situated US executives of the Company, in accordance with the Companyâ€™s policy and/or practice which as of the Effective Date is a flexible policy. 5.Business Expenses. The Company shall reimburse the Executive for all necessary and reasonable travel (which does not include commuting to Executiveâ€™s Principal Place of Employment) and other business expenses incurred by the Executive in the performance of his duties hereunder in accordance with such policies and procedures as the Company may adopt generally from time to time for executives. 6.Termination of Employment Without Cause; Resignation for Good Reason. If the Executiveâ€™s employment is terminated by the Company without Cause or by the Executive for Good Reason, the provisions of this Section 6 shall apply. (a)The Company may terminate the Executiveâ€™s employment with the Company at any time without Cause upon not less than thirty (30) daysâ€™ prior written notice to the Executive and the Executive may resign for Good Reason. (b)Unless the Executive complies with the provisions of Section 6(c) below, upon termination of employment under Section 6(a) above, no other payments or benefits shall be due under this Agreement to the Executive other than the Accrued Obligations. (c)Notwithstanding the provisions of Section 6(b) above, upon termination of employment under Section 6(a) above, if the Executive executes and does not revoke the Release, and so long as the Executive continues to comply with the provisions of Section 15 below, in addition to the Accrued Obligations, the Executive shall be entitled to receive the following: (i)Continuation of the Executiveâ€™s Base Salary for a twelve (12) month period (the â€œSeverance Termâ€), at the rate in effect for the year in which the Executiveâ€™s date of termination of employment occurs, which amount shall be paid in regular payroll installments over the Severance Term. 3Â Â (ii)If the Executive timely and properly elects health continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 (â€œCOBRAâ€), then continued health (including hospitalization, medical, dental, vision etc.) insurance coverage substantially similar in all material respects as the coverage provided to other Company employees for the Severance Term; provided that the Executive shall pay the employee portion of such coverage, if any, the period of COBRA health care continuation coverage provided under section 4980B of the Code shall run concurrently with the Severance Term, and notwithstanding the foregoing, the amount of any benefits provided by this subsection (ii) shall be reduced or eliminated to the extent the Executive obtains duplicative benefits by virtue of the Executiveâ€™s subsequent or other employment. Notwithstanding the foregoing, if the Companyâ€™s making payments under this Section 6(c) would violate any nondiscrimination rules applicable to the Companyâ€™s group health plan under which such coverage is made available, or result in the imposition of penalties under the Code or the Affordable Care Act, the Parties agree to reform this Section 6(c) in a manner as is necessary to comply with such requirements and avoid such penalties. (iii)An amount equal to the Target Annual Bonus, prorated for the portion of the performance period that the Executive was employed prior to such termination, payable within forty-five (45) days of Executiveâ€™s termination of employment; provided, that such termination occurs six months or more into the applicable performance period for such Annual Bonus. (iv)Any time-based equity awards shall accelerate and vest with respect to the number of shares underlying the equity awards that would vest over the Severance Term had the Executive remained employed for such Severance Term and any equity awards that are subject to performance-based vesting shall vest and become exercisable, if at all, subject to the terms of such equity awards. 7.Change in Control. Notwithstanding anything to the contrary herein, if there is a CIC Termination, then the provisions of this Section 7 shall apply. (a)Unless the Executive complies with the provisions of Section 7(b) below, upon CIC Termination, no other payments or benefits shall be due under this Agreement to the Executive other than the Accrued Obligations. (b)Notwithstanding the provisions of Section 7(a) above, upon CIC Termination, if the Executive executes and does not revoke the Release, and so long as the Executive continues to comply with the provisions of Section 15 below, then, in addition to the Accrued Obligations, the Executive shall be entitled to receive the following: (i)Continuation of the Executiveâ€™s Base Salary for a twelve (12) month period (the â€œCIC Severance Termâ€), at the rate in effect for the year in which the Executiveâ€™s date of termination of employment occurs, which amount shall be paid in regular payroll installments over the CIC Severance Term; (ii)An amount equal to the Annual Target Bonus, payable within forty-five (45) days of Executiveâ€™s termination of employment; 4Â Â (iii)COBRA continuation benefits as set forth in Section 6(c)(iii), except that the Severance Term shall be the CIC Severance Term; and (iv)All time-based equity awards shall accelerate and become fully vested and any equity awards that are subject to performance-based vesting shall vest, if at all, subject to the terms of such equity awards. 8.Cause. The Company may terminate the Executiveâ€™s employment at any time for Cause upon written notice to the Executive, in which event all payments under this Agreement shall cease, except for any Accrued Obligations. 9.Voluntary Resignation Without Good Reason. The Executive may voluntarily terminate employment without Good Reason upon 30 daysâ€™ prior written notice to the Company. In such event, after the effective date of such termination, no payments shall be due under this Agreement, except that the Executive shall be entitled to any Accrued Obligations. 10.Disability. If the Executive incurs a Disability during the Term, the Company may terminate the Executiveâ€™s employment on or after the date of Disability. If the Executiveâ€™s employment terminates on account of Disability, the Executive shall be entitled to receive any Accrued Obligations and if the Executive executes and does not revoke the Release, an amount equal to the Target Annual Bonus, prorated for the portion of the performance period that the Executive was employed prior to such termination for Disability; provided, that such termination occurs six months or more into the applicable performance period. For purposes of this Agreement, the term â€œDisabilityâ€ shall mean the Executive is eligible to receive long-term disability benefits under the Companyâ€™s long-term disability plan and if the Company does not have a long-term disability plan, shall mean the Executiveâ€™s inability, due to physical or mental incapacity, to perform the essential functions of Executiveâ€™s position, with or without reasonable accommodation, for 120 days out of any 365 day period. 11.Death. If the Executive dies during the Term, the Executiveâ€™s employment shall terminate on the date of death and the Company shall pay to the Executiveâ€™s executor, legal representative, administrator or designated beneficiary, as applicable, any Accrued Obligations. The Company shall have no further liability or obligation under this Agreement to the Executiveâ€™s executors, legal representatives, administrators, heirs or assigns or any other person claiming under or through the Executive. 12.Resignation of Positions. Effective as of the date of any termination of employment, the Executive will resign from all Company-related positions, including as an officer and director of the Company and its parent(s), subsidiaries, and Affiliates. 13.Definitions. For purposes of this Agreement, the following terms shall have the following meanings: (a)â€œAccrued Obligationsâ€ shall mean (i) any Base Salary earned through the Executiveâ€™s termination of employment that remains unpaid; (ii) any Annual Bonus payable with respect to any calendar year which ended prior to the effective date of the Executiveâ€™s termination of employment, which remains unpaid; (iii) in the event of a termination of employment as a result of death, an amount equal to the Target Annual Bonus, prorated for the portion of the performance period that the Executive was employed prior to such termination; provided, that such termination occurs six months or more into the applicable performance period for such Annual Bonus; or (iv) 5Â Â any accrued, unused personal time off days, if required to be paid out under the Company policies. The Accrued Obligations shall be paid following the Executiveâ€™s termination of employment at such times and in accordance with such policies as would normally apply to such amounts and regardless of whether the Executive executes or revokes the Release. (b)â€œCauseâ€ shall mean any of the following grounds for the Executiveâ€™s termination of employment listed: (i) the Executiveâ€™s knowing and material dishonesty or fraud committed in connection with the Executiveâ€™s employment; (ii) theft, misappropriation, or embezzlement by the Executive of the Companyâ€™s funds; (iii) the Executive repeatedly negligently performing or failing to perform, or willfully refusing to perform, the Executiveâ€™s duties to the Company (other than a failure resulting from Executiveâ€™s incapacity due to physical or mental illness); (iv) the Executiveâ€™s conviction of or a plea of guilty or nolo contendere to any felony, a crime involving fraud or misrepresentation, or any other crime (whether or not connected with his employment) the effect of which is likely to adversely affect the Company or its Affiliates; (v) a material breach by the Executive of any of the provisions or covenants set forth in this Agreement; (vi) a material breach by the Executive of the Companyâ€™s Code of Conduct and Business Ethics; or (vii) any other act or omission by the Executive that has a material adverse effect on the Companyâ€™s ability to operate. Prior to any termination of employment for Cause pursuant to each such event listed in (i), (iii), (v), (vi), or (vii) above, to the extent such event(s) is capable of being cured by the Executive, the Company shall give the Executive written notice thereof describing in reasonable detail the circumstances constituting Cause and the Executive shall have the opportunity to remedy same within thirty (30) days after receiving written notice. If the circumstances alleged to constitute Cause are remedied within the thirty (30) day cure period, no Cause shall exist to terminate Executive. (c)â€œChange in Controlâ€ shall have the meaning set forth in the Equity Plan. (d)â€œChange in Control Periodâ€ shall mean the period commencing 90 days prior to a Change in Control and ending on the first anniversary of such Change in Control. (e)â€œCIC Terminationâ€ shall mean termination of the Executiveâ€™s employment by the Company without Cause or by the Executive for Good Reason during the Change in Control Period, provided that, in either case, a Change in Control actually occurs. (f)â€œGood Reasonâ€ shall mean the occurrence of one or more of the following without the Executiveâ€™s consent, other than on account of the Executiveâ€™s Disability: (i)A material diminution by the Company of the Executiveâ€™s title authority, reporting structure, duties or responsibilities; (ii)A material change in the geographic location at which the Executive must perform services under this Agreement (which, for purposes of this Agreement, means relocation of the Executiveâ€™s Principal Place of Employment to a location that increases the Executiveâ€™s commute to work by more than 35 miles); (iii)A reduction in the Executiveâ€™s Base Salary (other than an across the board reduction of base salary for similarly situated senior level executives); or 6Â Â (iv)Any action or inaction that constitutes a material breach by the Company of this Agreement. The Executive must provide written notice of termination for Good Reason to the Company within 30 days after the event constituting Good Reason. The Company shall have a period of 30 days in which it may correct the act or failure to act that constitutes the grounds for Good Reason as set forth in the Executiveâ€™s notice of termination. If the Company does not correct the act or failure to act, the Executiveâ€™s employment will terminate for Good Reason on the first business day following the Companyâ€™s 30-day cure period. (g)â€œReleaseâ€ shall mean a separation agreement and general release of any and all claims against the Company and its Affiliates with respect to all matters arising out of the Executiveâ€™s employment by the Company, and the termination thereof (other than claims for any entitlements under the terms of this Agreement or under any plans or programs of the Company under which the Executive has accrued and is due a benefit). The Release will be in form and substance specified by and acceptable to the Company and Executive, and will include provisions in which the Executive shall reaffirm and agree to remain bound by the restrictive covenants set forth in Section 15 below. Such general release shall be executed and delivered (and no longer subject to the 7 business day revocation period) by the Executive within sixty (60) days following delivery of the general release to the Executive. 14.Section 409A. (a)This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended (the â€œCodeâ€), and its corresponding regulations, or an exemption thereto, and payments may only be made under this Agreement upon an event and in a manner permitted by section 409A of the Code, to the extent applicable. Severance benefits under this Agreement are intended to be exempt from section 409A of the Code under the â€œshort-term deferralâ€ exception, to the maximum extent applicable, and then under the â€œseparation payâ€ exception, to the maximum extent applicable. Notwithstanding anything in this Agreement to the contrary, if required by section 409A of the Code, if the Executive is considered a â€œspecified employeeâ€ for purposes of section 409A of the Code and if payment of any amounts under this Agreement is required to be delayed for a period of six months after separation from service pursuant to section 409A of the Code, payment of such amounts shall be delayed as required by section 409A of the Code, and the accumulated amounts shall be paid in a lump-sum payment within 10 days after the end of the six-month period. If the Executive dies during the postponement period prior to the payment of benefits, the amounts withheld on account of section 409A of the Code shall be paid to the personal representative of the Executiveâ€™s estate within 60 days after the date of the Executiveâ€™s death. (b)All payments to be made upon a termination of employment under this Agreement may only be made upon a â€œseparation from serviceâ€ under section 409A of the Code. For purposes of section 409A of the Code, each payment hereunder shall be treated as a separate payment, and the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments. In no event may the Executive, directly or indirectly, designate the fiscal year of a payment. Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of the Executiveâ€™s execution of the Release, directly or indirectly, result in the Executiveâ€™s designating the fiscal year of payment of any amounts of deferred compensation 7Â Â subject to section 409A of the Code, and if a payment that is subject to execution of the Release could be made in more than one taxable year, payment shall be made in the later taxable year. (c)All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of section 409A of the Code, including, where applicable, the requirement that (i) any reimbursement be for expenses incurred during the period specified in this Agreement, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during a fiscal year not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other fiscal year, (iii) the reimbursement of an eligible expense be made no later than the last day of the fiscal year following the year in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits not be subject to liquidation or exchange for another benefit. 15.Restrictive Covenants. (a)Noncompetition. The Executive agrees that during the Executiveâ€™s employment with the Company and its Affiliates and (i) the CIC Severance Term after a CIC Termination and (ii) for any other termination of employment, including a termination of employment where severance is not payable to the Executive, the number of calendar months during the period of the Severance Term (the â€œRestriction Periodâ€), the Executive will not, without the Parent Boardâ€™s express written consent, engage (directly or indirectly) in any Competitive Business in the United States or Canada. The term â€œCompetitive Businessâ€ means any person, concern or entity which is engaged in or conducts a business substantially the same as the Business of the Company and its Affiliates. The term â€œBusinessâ€ means the discovery, research, development and commercialization of gene therapy treatments currently under active discovery, development or commercialization at the Company (generally referred to internally as â€œProgramsâ€ and â€œPipelineâ€), including material external sponsored research agreements. The Executive understands and agrees that, given the nature of the business of the Company and its Affiliates and the Executiveâ€™s position with the Company, the foregoing scope is reasonable and appropriate, and necessary to protect the Companyâ€™s legitimate business interests. For purposes of this Agreement, the term â€œAffiliateâ€ means any subsidiary of the Company or Parent or any other entity under common control with the Company. The Executive and the Company agree that the terms set forth in this Agreement, including without limitation, the Base Salary, the Annual Bonus opportunity and severance rights that the Company is awarding the Executive as consideration for the covenants in this Section 15(a) are mutually-agreed upon consideration for the Executiveâ€™s compliance with this Section 15(a). (b)Nonsolicitation of Company Personnel. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, hire or attempt to hire any employee of the Company or its Affiliates, or solicit or attempt to solicit any such person to change or terminate his or her relationship with the Company or an Affiliate or otherwise to become an employee, consultant or independent contractor to, for or of any other person or business entity; provided that the foregoing does not prohibit general solicitation or recruitment activities not directed at employees of the Company or soliciting, recruiting or hiring any person who responds thereto. (c)Nonsolicitation of Customers. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, solicit, divert or appropriate, or attempt to solicit, divert or appropriate, any customer of the Company or an Affiliate for the 8Â Â purpose of providing such customer with services or products competitive with those offered by the Company or an Affiliate during the Executiveâ€™s employment with the Company or an Affiliate. (d)Proprietary Information. At all times, the Executive will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Proprietary Information (defined below) of the Company or an Affiliate, except as such disclosure, use or publication may be required in connection with the Executiveâ€™s work for the Company or as described in Section 15(e) below, or unless the Company expressly authorizes such disclosure in writing. â€œProprietary Informationâ€ shall mean any and all confidential and/or proprietary knowledge, data or information of the Company and its Affiliates and shareholders, including but not limited to information relating to financial matters, investments, budgets, business plans, marketing plans, personnel matters, business contacts, products, processes, know-how, designs, methods, improvements, discoveries, inventions, ideas, data, programs, and other works of authorship. For purposes of this Agreement, the term â€œProprietary Informationâ€ shall not include information which is or becomes publicly available without breach of: (i) this Agreement; (ii) any other agreement or instrument to which the Company or an Affiliate is a party or a beneficiary; or (iii) any duty owed to the Company or an Affiliate by the Executive or by any third party. It shall also not include any information that was known to Executive prior to Executiveâ€™s employment with the Company and which was communicated to the Company in writing; provided, however, that if the Executive shall desire or seek to disclose, use, lecture upon, or publish any Proprietary Information, the Executive shall bear the burden of proving that any such information shall have become publicly available without any such breach. (e)Reports to Government Entities. Nothing in this Agreement shall prohibit or restrict the Executive from initiating communications directly with, responding to any inquiry from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the Equal Employment Opportunity Commission, the Department of Labor, the

National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, Congress, any agency Inspector General or any other federal, state or local regulatory authority (collectively, the â€œRegulatorsâ€), or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. The Executive does not need the prior authorization of the Company to engage in conduct protected by this subsection, and the Executive does not need to notify the Company that the Executive has engaged in such conduct. Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose trade secrets to their attorneys, courts, or government officials in certain, confidential circumstances that are set forth at 18 U.S.C. Â§Â§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law. (f)Inventions Assignment. The Executive agrees that all inventions, innovations, improvements, developments, methods, designs, analyses, reports, and all related information which relates to the Companyâ€™s or its Affiliatesâ€™ actual business, research and development of existing or future products or services and which are actually being developed or made by the Executive while employed by the Company, on Company time and using Company resources (â€œWork Productâ€) belong to the Company. The Executive will perform all actions reasonably requested by the Parent Board (whether during or after the Term) to establish and confirm such 9Â Â ownership (including, without limitation, assignments, consents, limited powers of attorney and other instruments). If requested by the Company, the Executive agrees to execute any inventions assignment and confidentiality agreement that is required to be signed by Company employees generally. (g)Return of Company Property. Within a reasonable time after termination of the Executiveâ€™s employment with the Company for any reason, and at any earlier time the Company requests, the Executive will deliver to the person designated by the Company all originals and copies of all documents and property of the Company or an Affiliate that are in the Executiveâ€™s possession or under the Executiveâ€™s control or to which the Executive may have access. The Executive will not reproduce or appropriate for the Executiveâ€™s own use, or for the use of others, any property, proprietary information, or Work Product. (h)Restrictive Covenant Acknowledgement. The Executive acknowledges and agrees that the foregoing restrictions contained in Section 15 are reasonable, proper and necessitated by the legitimate business interests of the Company and will not prevent the Executive from earning a living or pursuing a career. In the event that a court of competent jurisdiction determines that any of the provisions of this Agreement (including, without limitation, the provisions of Section 15) would be unenforceable as written because they cover too extensive a geographic area, too broad a range of activities, too long a period of time, insufficient consideration, or otherwise, then such provisions automatically shall be modified to cover the maximum geographic area, range of activities, and period of time as may be enforceable, and the minimum amount of required consideration as may be enforceable, and in addition, such court is hereby expressly authorized so to modify this Agreement and to enforce it as so modified. 16.Legal and Equitable Remedies. Because the Executiveâ€™s services are personal and unique and the Executive has had and will continue to have access to and has become and will continue to become acquainted with the proprietary information of the Company and its Affiliates, and because any breach by the Executive of any of the restrictive covenants contained in Section 15 would result in irreparable injury and damage for which money damages would not provide an adequate remedy, the Company shall have the right to seek to enforce Section 15 and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach, or threatened breach, of the restrictive covenants set forth in Section 15. The Executive agrees that in any action in which the Company seeks injunction, specific performance or other equitable relief, the Executive will not assert or contend that any of the provisions of Section 15 are unreasonable or otherwise unenforceable. 17.Survival. The respective rights and obligations of the parties under this Agreement (including, but not limited to, under Sections 15 and 16) shall survive any termination of the Executiveâ€™s employment or termination or expiration of this Agreement to the extent necessary to the intended preservation of such rights and obligations. 18.No Mitigation or Set-Off. In no event shall the Executive be obligated to seek other employment or take any other action by way of mitigation of the amounts payable to the Executive under any of the provisions of this Agreement, and such amounts shall not be reduced regardless of whether the Executive obtains other employment. The Companyâ€™s obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall 10Â Â not be affected by any circumstances, including, without limitation, any set-off, counterclaim, recoupment, defense or other right which the Company may have against the Executive or others. 19.Section 280G. In the event of a change in ownership or control under section 280G of the Code, if it shall be determined that any payment or distribution in the nature of compensation (within the meaning of section 280G(b)(2) of the Code) to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a â€œPaymentâ€), would constitute an â€œexcess parachute paymentâ€ within the meaning of section 280G of the Code, the aggregate present value of the Payments under this Agreement shall be reduced (but not below zero) to the Reduced Amount (defined below) if and only if the Accounting Firm (described below) determines that the reduction will provide the Executive with a greater net after-tax benefit than would no reduction. No reduction shall be made unless the reduction would provide Executive with a greater net after-tax benefit. The determinations under this Section shall be made as follows: (a)The â€œReduced Amountâ€ shall be an amount expressed in present value which maximizes the aggregate present value of Payments under this Agreement without causing any Payment under this Agreement to be subject to the Excise Tax (defined below), determined in accordance with section 280G(d)(4) of the Code. The term â€œExcise Taxâ€ means the excise tax imposed under section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax. (b)Payments under this Agreement shall be reduced on a nondiscretionary basis in such a way as to minimize the reduction in the economic value deliverable to the Executive. Where more than one payment has the same value for this purpose and they are payable at different times, they will be reduced on a pro rata basis. Only amounts payable under this Agreement shall be reduced pursuant to this Section. (c)All determinations to be made under this Section shall be made by an independent certified public accounting firm selected by the Company and agreed to by the Executive immediately prior to the change-in-ownership or -control transaction (the â€œAccounting Firmâ€). The Accounting Firm shall provide its determinations and any supporting calculations both to the Company and the Executive within 10 days of the transaction. Any such determination by the Accounting Firm shall be binding upon the Company and the Executive. All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section shall be borne solely by the Company. 20.Tax Equalization. The Company will reimburse the Executive for all reasonable and necessary costs incurred in connection with any cross-border tax filings that may be required, as well as the cost of joining the NEXUS program and any other visa or related issues with respect to the Executiveâ€™s employment with the Company. To the extent the Executive is subject to additional taxes in respect of services performed in Canada (whenever such services were performed on the Companyâ€™s behalf), the Company will reimburse the Executive for such additional taxes with an appropriate gross up calculation such that the Executive pays no more income taxes in respect of compensation from the Company then the Executive would have paid had the services solely been performed in the United States. Without limiting any of the foregoing provisions of this Section 20, the Company hereby agrees to fully indemnify the Executive against: (i) any and all tax liability that the Executive incurs in Canada arising with respect to any services that Executive performs in Canada for and on behalf of the Company, Parent or any of their 11Â Â respective subsidiaries, (ii) any and all tax liability that Executive incurs in the United States by virtue of Parent or any of its subsidiaries being a Passive Foreign Investment Company and that Executive would not have incurred if each of Parent and its subsidiaries were a corporation incorporated and existing under the laws of a State in the United States, and (iii) any other tax liability or penalties that Executive incurs in the United States or Canada by virtue of the Parent or any of its subsidiaries being a Canadian corporation and that Executive would not have incurred if each of Parent and its subsidiaries were a corporation incorporated and existing under the laws of a State in the United States. 21.Notices. All notices and other communications required or permitted under this Agreement or necessary or convenient in connection herewith shall be in writing and shall be deemed to have been given when emailed, hand delivered or mailed by registered or certified mail, as follows (provided that notice of change of address shall be deemed given only when received): If to the Company, to: 200 Fifth Avenue Suite 4020 Waltham, MA 02451 Attn: Chief Legal Officer If to the Executive, to the most recent address on file with the Company or to such other names or addresses as the Company or the Executive, as the case may be, shall designate by notice to each other person entitled to receive notices in the manner specified in this Section. 22.Withholding. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, state and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. The Executive shall bear all expense of, and be solely responsible for, all federal, state and local taxes due with respect to any payment received under this Agreement. 23.Remedies Cumulative; No Waiver. No remedy conferred upon a party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given under this Agreement or now or hereafter existing at law or in equity. No delay or omission by a party in exercising any right, remedy or power under this Agreement or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in its sole discretion. 24.Binding Arbitration and Waiver of Right to Participate in Class Actions. Except for disputes relating to, or arising out of, the Executiveâ€™s obligations set forth in Section 15, including the Companyâ€™s right to independently seek and obtain injunctive relief in state or federal courts, the parties agree to arbitrate any and all claims, disputes or controversies relating to, or arising out of, or concerning, this Agreement and/or the Executiveâ€™s employment with the Company, including termination of the Executiveâ€™s employment. If either party initiates arbitration, the initiating party must notify the other party in writing via U.S. mail, or hand delivery within the applicable statute of limitations period under Massachusetts law. The partiesâ€™ agreement to arbitrate employment-related claims is intended to include, but is not limited to, claims concerning compensation, benefits or other terms and conditions of employment, or any other claims whether arising by statute or otherwise including, but not limited to, employment claims of wrongful 12Â Â discharge, discrimination, harassment or retaliation under federal, state or local laws including, without limitation, Commonwealth of Massachusetts; Title VII of the Civil Rights Act as amended, the Equal Pay Act, the Americans With Disabilities Act (as amended), the Age Discrimination in Employment Act, the Older Workers Benefits Protection Act; the Patient Protection and Affordable Care Act, and claims arising under the Fair Labor Standards Acts, or any other national, federal, state or local employment or discrimination laws, rules or regulations. The Executiveâ€™s agreement to arbitrate also includes claims for breach of contract, violation of internal procedure or policy, wrongful termination in violation of public policy, wrongful discharge or termination, tort claims including negligence, defamation, loss of reputation, interference with contractual relations or prospective economic advantage, retaliation, and negligent or intentional infliction of emotional distress. The Executive agrees that all such claims will be fully and finally resolved by mandatory, binding arbitration conducted by the American Arbitration Association (â€œAAAâ€) located within thirty miles of the Executiveâ€™s Principal Place of Employment, pursuant to the AAA then-current Employment Arbitration Rules and Mediation Procedures. A copy of those rules is available online at www.adr.org/aaa. The Company as the employer will bear the administrative costs and arbitrator fees, and the arbitrator in such action may award whatever remedies would be available to the parties in a court of law. The purpose of this provision is to require binding arbitration of such disputes, claims or controversies that are or may be arbitrable, and the inclusion of any claim in this provision as to which a jury trial or civil action may not be waived will not taint or invalidate the remainder of this provision. To be clear, this agreement to arbitrate does not apply to any lawsuit to enforce this arbitration clause, or, as referenced above, to seek relief as set forth in Section 15 of this Agreement. Those lawsuits will be commenced in the state or federal courts sitting in the Commonwealth of Massachusetts and the Executive consents to the jurisdiction of the federal or state courts of Massachusetts. 25.Assignment. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective heirs, executors, administrators, legal representatives, successors and assigns of the parties hereto, except that the duties and responsibilities of the Executive under this Agreement are of a personal nature and shall not be assignable or delegable in whole or in part by the Executive. The Company may assign its rights, together with its obligations hereunder, in connection with any sale, transfer or other disposition of all or substantially all of its business and assets, and such rights and obligations shall inure to, and be binding upon, any successor to the business or any successor to substantially all of the assets of the Company, whether by merger, purchase of stock or assets or otherwise, which successor shall expressly assume such obligations, and the Executive acknowledges that in such event the obligations of the Executive hereunder, including but not limited to those under Section 15, will continue to apply in favor of the successor. 26.Company Policies. This Agreement and the compensation payable hereunder shall be subject to any applicable clawback or recoupment policies, share trading policies, and other policies that may be implemented by the Parent Board from time to time with respect to officers of the Company. 27.Indemnification. In the event the Executive is made, or threatened to be made, a party to any legal action or proceeding, whether civil or criminal, including any governmental or regulatory proceedings or investigations, by reason of the fact that the Executive is or was a director or officer of the Company or any of its Affiliates, the Executive shall be fully indemnified by the Company, and the Company shall pay the Executiveâ€™s related expenses (including reasonable attorneysâ€™ fees, 13Â Â judgments, fines, settlements and other amounts incurred in connection with any proceeding arising out of) when and as incurred, to the fullest extent permitted by applicable law and the Companyâ€™s articles of incorporation and bylaws. During the Executiveâ€™s employment with the Company or any of its Affiliates and after termination of employment for any reason, the Company shall cover the Executive under the Companyâ€™s directorsâ€™ and officersâ€™ insurance policy applicable to other officers and directors according to the terms of such policy. Such obligations shall be binding upon the Companyâ€™s successors and assigns and shall inure to the benefit of the Executiveâ€™s heirs and personal representatives. 28.Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto and supersedes any and all prior agreements and understandings concerning the Executiveâ€™s employment by the Company. This Agreement may be changed only by a written document signed by the Executive and the Company. 29.Severability. If any provision of this Agreement or application thereof to anyone or under any circumstances is adjudicated to be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect any other provision or application of this Agreement, which can be given effect without the invalid or unenforceable provision or application, and shall not invalidate or render unenforceable such provision or application in any other jurisdiction. If any provision is held void, invalid or unenforceable with respect to particular circumstances, it shall nevertheless remain in full force and effect in all other circumstances. 30.Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive and procedural laws of the Commonwealth of Massachusetts without regard to rules governing conflicts of law. 31.Counterparts. This Agreement may be executed in any number of counterparts (including facsimile counterparts), each of which shall be an original, but all of which together shall constitute one instrument. 32.Acknowledgments. The Executive acknowledges that (a) the Executive has the right to consult with counsel prior to signing this Agreement and has had a full and adequate opportunity to read, understand and discuss with the Executiveâ€™s advisors, including counsel, the terms and conditions contained in this Agreement prior to signing hereunder, (b) this Agreement is supported by fair and reasonable consideration independent from the continuation of employment, and (c) the Executive received notice of this Agreement at least ten business days before it is to be effective. (Signature Page Follows) 14Â Â IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written. ENGENE USA, INC. Â /s/ Ronald H. W. Cooper Name: Ronald H. W. Cooper Title: Chief Executive Officer Date: October 16, 2024 Â EXECUTIVE Â /s/ Joan Connolly Name: Joan Connolly Date: October 16, 2024 Â Â 15Â EX-10.34 4 engn-ex10_34.htm EX-10.34 EX-10.34 Exhibit 10.34 October 16, 2024 (revised as requested on October 30, 2024) Â By Email Â James Sullivan (by email) Â RE: Separation Agreement and General Release Â Dear Jim: Â This letter of agreement and general release ("Agreement") confirms our mutual agreement regarding the terms and conditions of your separation from employment with enGene USA, Inc. (â€œenGeneâ€ or the â€œCompanyâ€). You and the Company agree as follows: Â 1.Last Day of Employment. Your last day of employment with the Company will be October 31, 2024 (â€œLast Day of Employmentâ€). You will receive your salary at your regular rate of pay through your Last Day of Employment. Your employment and your participation in the Company's employee benefit plans and programs will terminate on your Last Day of Employment. Â 2.Severance Benefits. Provided that you (i) timely sign this Agreement after your Last Day of Employment and do not revoke this Agreement, (ii) return all Company property, (iii) provide all administrative information, including all login controls, regarding all accounts you used or accessed related to your work for the Company, and (iv) otherwise comply with your obligations under this Agreement and your continuing obligations to the Company under Sections 15 and 16 of your Employment Agreement with the Company dated November 8, 2023 (the â€œEmployment Agreementâ€), you shall be entitled to the following: Â a.Continuation of your Base Salary for a twelve (12) month period (the â€œSeverance Termâ€), in the total amount of $485,000 less applicable taxes and withholdings, which amount shall be paid in regular payroll in accordance with the Company's normal payroll practices. Payment will begin with the first regular payroll date reasonably practicable to process payment following the Effective Date of this Agreement, and any installments not paid between the Last Day of Employment and the date of the first payment will be paid with the first payment. Â b.Subject to your copayment of premium amounts at the applicable active employeesâ€™ rate and your proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (â€œCOBRAâ€), the Company will pay to the group health plan provider(s) or the COBRA provider a monthly payment equal to the monthly employer contribution that the Company would have made to provide family health (including hospitalization, medical, dental, vision, etc.) insurance to you if you had remained employed by the Company until the earliest of (A) the twelfth (12th) month anniversary of your Last Day of Employment; (B) your eligibility for group health plan benefits under any other employer's group health plan; or (C) the cessation of your continuation rights under COBRA; provided, however, that if the Company reasonably determines that it cannot pay such amounts to the group health plan provider(s) or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 1Â Â 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above (such payments, if to you, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates). Â c.An amount equal to your Target Annual Bonus of 40% of your annual Base Salary as defined in your Employment Agreement, prorated for the portion of the performance period that you were employed in 2024, payable within forty-five (45) days of your Last Day of Employment. Â d.Your time-based equity awards shall accelerate and vest with respect to the number of shares underlying the equity awards that would vest over the Severance Term had you remained employed for such Severance Term (such that an aggregate 20,742 shares that would have vested from November 1, 2024 through October 31, 2025 shall immediately become vested) and any equity awards that are subject to performance-based vesting shall vest and become exercisable, if at all, subject to the terms of such equity awards. Â e.The Company will seek approval of the Board of Directors (the "Board") of enGene Holdings Inc., which such approval shall not unreasonably be withheld, to extend the post-termination exercise period for all your outstanding stock options until October 31, 2025 (it being understood and agreed that if you exercise, at any time after the third month following your Last Date of Employment, any of such stock options that would otherwise qualify as incentive stock options, shall automatically cease to be incentive stock options and shall automatically become and be treated as non-qualified stock options for purposes of United States federal and state income taxes). Â / 3. Release. Â a)In consideration of the benefits set forth herein, including but not limited to the benefits set forth in Paragraph 2, to the fullest extent permitted by law you waive, release and forever discharge the Company and each of its past and current parents, subsidiaries, affiliates, and each of its and their respective past and current directors, officers, members, trustees, employees, representatives, agents, attorneys, employee benefit plans and such plans' administrators, fiduciaries, trustees, recordkeepers and service providers, and each of its and their respective successors and assigns, each and all of them in their personal and representative capacities (collectively the "Company Releasees") from any and all claims legally capable of being waived, grievances, injuries, controversies, agreements, covenants, promises, debts, accounts, actions, causes of action, suits, arbitrations, sums of money, attorneys' fees, costs, damages, or any right to any monetary recovery or any other personal relief, whether known or unknown, in law or in equity, by contract, tort, law of trust or pursuant to federal, state or local statute, regulation, ordinance or common law, which you now have, ever have had, or may hereafter have, based upon or arising from any fact or set of facts, whether known or unknown to you, from the beginning of time until the date of execution of this Agreement arising out of or relating in any way to your employment relationship with the Company or any termination thereof. For the avoidance of doubt, the "Company Releasees" includes enGene Holdings, Inc. Â 2Â Â b)Without limiting the generality of the foregoing, this waiver, release, and discharge includes any claim or right, to the extent legally capable of being waived, based upon or arising under any federal, state or local fair employment practices or equal opportunity laws, including, but not limited to, the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act, the Rehabilitation Act of 1973, the Worker Adjustment and Retraining Notification Act, 42 U.S.C. Section 1981, Title VII of the Civil Rights Act of 1964, the Equal Pay Act, the Employee Retirement Income Security Act ("ERISA") (including, but not limited to, claims for breach of fiduciary duty under ERISA), the Americans With Disabilities Act, the Family and Medical Leave Act of 1993, the Massachusetts Fair Employment Practices Act, the Massachusetts Civil Rights Act, the Massachusetts Equal Rights Act, the Massachusetts Labor and Industries Act, the Massachusetts Earned Sick Time Law, the Massachusetts Right of Privacy Law, the Massachusetts Wage Act (as further explained below), the Massachusetts Paid Family and Medical Leave Act, and the Massachusetts Minimum Fair Wage Law, including all amendments thereto. Â c)Massachusetts Wage Act Waiver. By signing this Agreement, you acknowledge that this waiver includes any claims against the Company Releasees under Mass. Gen. Laws ch. 149, Â§ 148 et seq., - the Massachusetts Wage Act. These claims include, but are not limited to, claims for failure to pay earned wages, failure to pay overtime, failure to pay earned commissions, failure to timely pay wages, failure to pay accrued vacation or holiday pay, failure to furnish appropriate pay stubs, improper wage deductions, and failure to provide proper check-cashing facilities. Â d)Age Claim Waiver. In addition to all other claims released under this Agreement, you understand and agree that you are waiving all claims available against the Company Releasees arising out of your employment with the Company or the termination of your employment under the ADEA and OWBPA. Â e)You also agree to waive any right to bring, maintain, or participate in a class action. collective action, or representative action against the Company and/or the other Company Releasees to the fullest extent permitted by law. You agree that you may not serve as a representative of a class action, collective action, or representative action. may not participate as a member of a class action. collective action, or representative action. and may not recover any relief from a class action, collective action, or representative action. You further agree that if you are included within a class action, collective action, or representative action, you will take all steps necessary to opt-out of the action or refrain from opting in, as the case may be. You are not waiving any right to challenge the validity of this Paragraph 3(e) on any grounds that may exist in law and equity. However, the Company and the other Company Releasees reserve the right to attempt to enforce this Agreement, including this Paragraph 3(e), in any appropriate forum. Â f)Notwithstanding the generality of the foregoing, nothing herein constitutes a release or waiver by you of, or prevents you from making or asserting: (i) any claim or right you may have under COBRA; (ii) any claim or right you may have for unemployment insurance or workers' compensation benefits (other than for retaliation under workers' compensation laws); (iii) any claim to vested benefits under the written terms of a qualified employee pension benefit plan; (iv) any medical claim incurred during your employment that is 3Â Â payable under applicable medical plans or an employer-insured liability plan; (v) any claim or right that may arise after the execution of this Agreement; (vi) any claim or right you may have under this Agreement; (vii) any claim or right to indemnification by the Company; (viii) any claim for benefits under paragraph 20 of the Employment Agreement; or (ix) any claim that is not otherwise waivable under applicable law. In addition, nothing herein shall prevent you from filing a charge or complaint with the Equal Employment Opportunity Commission ("EEOC") or similar federal or state fair employment practices agency or interfere with your ability to participate in any investigation or proceeding conducted by such agency; provided, however, that pursuant to this Paragraph 3, you are waiving any right to recover monetary damages or any other form of personal relief from the Company Releasees to the extent any such charge, complaint, investigation or proceeding asserts a claim subject to the releases herein. Â g)You acknowledge that you have not made any claims or allegations against any Company Releasee, the factual foundation for which involves sexual harassment or sexual assault or abuse. Â h)Release of Unknown Claims. You understand that the foregoing releases shall be effective as a full and final accord and satisfaction and general release of all claims, whether known or unknown, against the Company Releasees. You are aware that you may hereafter discover claims or facts in addition to or different from those you now know or believe to exist with respect to the subject matter of this Agreement which if you had known now, may have affected your decision to sign this Agreement; however, you hereby settle and release all of the claims which you had, have or may have against the Company and the other Company Releasees including arising out of such additional or different facts. Â 4.No Additional Entitlements. You agree and represent that you have received all entitlements due from the Company relating to your employment with the Company, including but not limited to, all wages earned, including without limitation all commissions and bonuses, severance, sick pay, vacation pay, overtime pay, and any paid and unpaid personal leave for which you were eligible and entitled, and that no other entitlements are due to you other than as set forth in this Agreement. Â 5.Return of Property. Before your Last Day of Employment, you will return to the Company all of its property, including, but not limited to, computers, cell phones, files, and documents, including any correspondence or other materials containing trade secrets of the Company, identification cards, credit cards, keys, equipment, software and data, however stored. To the extent you have any Company information or material stored on any PDA, personal computer, personal email, hard drive, thumb drive, cloud or other electronic storage device, you agree to cooperate with the Company in permanently deleting such information from such devices, subject to any Company litigation preservation directive then in effect. Â 6.Protection of Confidential Information. Except as expressly permitted in Paragraph 8 of this Agreement or if otherwise required by law, you agree that you will not at any time, directly or indirectly, disclose any trade secret, confidential or proprietary information you have learned by reason of your association with the Company. You further agree to comply fully with your continuing obligations to the Company under Sections 15 and 16 of your Employment Agreement, which are hereby incorporated herein by reference. Without 4Â Â limiting the generality of the foregoing, you agree that for one year from your Last Day of Employment, you will not, without the Board's express written consent, engage (directly or indirectly) in any Competitive Business (as defined in your Employment Agreement) in the United States or Canada. Â 7.Non-Disparagement. Except as expressly permitted in Paragraph 8 of this Agreement, you will not at any time make any written or oral comments or statements of a defamatory or disparaging nature regarding the Company and/or the other Company Releasees or their personnel and you shall not take any action that would cause the Company and/or the other Company Releasees or their personnel any embarrassment or humiliation or otherwise cause or contribute to their being held in disrepute. Notwithstanding the above, nothing in this paragraph or elsewhere in this Agreement should be read to prevent you from exercising your rights under Section 7 of the National Labor Relations Act. Â 8.Reports to Government Entities. Nothing in this Agreement restricts or prohibits you or anyone else from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including without limitation, the EEOC, the Department of Labor, the National Labor Relations Board, the U.S. Department of Justice, the U.S. Securities and Exchange Commission, the Financial Industry Regulatory Authority, the Occupational Safety and Health Administration, the U.S. Congress, any other federal, state, or local government agency or commission, and any agency Inspector General (collectively, the "Regulators"), or from making other disclosures that are protected under the whistleblower provisions of federal, state, or local law or regulation. You do not need the prior authorization of the Company to engage in conduct protected by this Paragraph, and you do not need to notify the Company that you have engaged in such conduct. This Agreement does not limit your right to receive an award from any Regulator that provides awards for providing information relating to a potential violation of the law. However, to the maximum extent permitted by law, you are waiving your right to receive any individual monetary relief from the Company or any other Company Releasee (as defined above in Paragraph 3) resulting from the released claims, regardless of whether you or another party has filed them, and in the event you obtain such monetary relief, the Company will be entitled to an offset for the benefits made pursuant to this Agreement. You recognize and agree that, in connection with any such activity outlined above, you must inform the Regulators, your attorney, a court or a government official that the information you are providing is confidential. Despite the foregoing, you are not permitted to reveal to any third-party, including any governmental, law enforcement, or regulatory authority, information you came to learn during the course of your employment with the Company that is protected from disclosure by any applicable privilege, including but not limited to the attorney-client privilege and/or attorney work product doctrine. The Company does not waive any applicable privileges or the right to continue to protect its privileged attorney-client information, attorney work product, and other privileged information. Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose a trade secret to their attorney, a court, or a government official in certain, confidential circumstances that are set forth at 18 U.S.C. Â§Â§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law. 5Â Â Â 9.Non-Admission. It is understood and agreed that neither the execution of this Agreement nor the terms of this Agreement constitute an admission of liability to you by the Company or the other Company Releasees, and such liability is expressly denied. It is further understood and agreed that no person shall use the Agreement, or the consideration paid pursuant thereto, as evidence of an admission of liability, inasmuch as such liability is expressly denied. Â 10.Cooperation. You agree that upon the Company's reasonable notice to you and at reasonable times that will not interfere with your business or personal matters, you shall cooperate with the Company and its counsel (including, if necessary, preparation for and appearance at depositions, hearings, trials or other proceedings) with regard to matters that relate to or arise out of matters you have knowledge about or have been involved with during your employment with the Company. In the event that such cooperation is required, you will be reimbursed for any reasonable travel expenses incurred in connection therewith. Â 11.Confidentiality of the Agreement. Except as permitted in Paragraph 8 of this Agreement or if otherwise required by law, the parties, including the Company, shall not disclose the terms of this Agreement, or the circumstances giving rise to this Agreement, to any person other than their respective attorneys, immediate family members, accountants, auditors, financial advisors or corporate employees who have a business need to know such terms in order to approve or implement such terms. Â 12.Acknowledgments. You hereby acknowledge that: Â a)The Company hereby advises you of your right to obtain independent legal advice from an attorney of your own choice with respect to this Agreement; b)You have obtained independent legal advice from an attorney of your own choice with respect to this Agreement; c)You freely, voluntarily and knowingly enter into this Agreement after due consideration; d)You have had a minimum of twenty one (21) days to review and consider this Agreement; e)You and the Company agree that changes to the Company's offer contained in this Agreement, whether material or immaterial, will not restart the twenty-one (21) day consideration period provided for above; f)You have a right to revoke this Agreement by notifying the undersigned representative in writing, via electronic mail, within seven (7) business days of your execution of this Agreement; g)In exchange for your waivers, releases and commitments set forth herein, including your waiver and release of all claims arising under the ADEA, the consideration that you are receiving pursuant to this Agreement exceeds any payment, benefit or other thing of value to which you would otherwise be entitled, and are just and sufficient consideration for the waivers, releases and commitments set forth herein; and h)No promise or inducement has been offered to you, except as expressly set forth herein, and you are not relying upon any such promise or inducement in entering into this Agreement. Â 13.Medicare Disclaimer. You acknowledge that you are not a Medicare Beneficiary as of the time you enter into this Agreement. To the extent that you are a Medicare Beneficiary, you agree to contact the undersigned for further instruction. 6Â Â Â 14.Miscellaneous. Â a)Entire Agreement. This Agreement sets forth the entire agreement between you and the Company and replaces any other oral or written agreement between you and the Company relating to the subject matter of this Agreement, including, without limitation, any prior offer letters and/or employment agreements, except for your continuing obligations to the Company under your Employment Agreement. Â b)Governing Law. This Agreement shall be construed, performed, enforced and in all respects governed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflicts of law thereof. Â c)Severability. Should any provision of this Agreement be held to be void or unenforceable, the remaining provisions shall remain in full force and effect, to be read and construed as if the void or unenforceable provisions were originally deleted. Â d)Amendments. This Agreement may not be modified or amended, except upon the express written consent of both you and the Company. Â e)Waiver. A waiver by either party hereto of a breach of any term or provision of the Agreement shall not be construed as a waiver of any subsequent breach. Â f)Counterparts. This Agreement may be executed electronically and in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement. Â g)Effective Date. This Agreement will become effective and enforceable upon the expiration of the seven business (7) day revocation period referred to above {the "Effective Date"). Â If the above accurately states our agreement, kindly sign below after your Last Day of Employment and return the original Agreement to me by November 21, 2024. Â Sincerely, enGene USA, Inc. Â By: /s/ Lee G. Giguere Lee G. Giguere Chief Legal Officer Â UNDERSTOOD, AGREED TO AND ACCEPTED WITH THE INTENTION TO BE LEGALLY BOUND: Â Â /s/ James Sullivan James Sullivan Date: Nov. 4, 2024 7Â Â EX-10.36 5 engn-ex10_36.htm EX-10.36 EX-10.36 Â Exhibit 10.36 CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. Â FIRST AMENDMENT TO AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT THIS FIRST AMENDMENT TO AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT (this â€œAmendmentâ€), dated as of December 18, 2024 (the â€œFirst Amendment Effective Dateâ€), is entered into by and among enGene Holdings Inc., a public corporation continued under the laws of British Columbia (â€œHoldingsâ€), enGene Inc., a corporation organized under the laws of Canada (â€œenGeneâ€), and Engene USA, Inc., a Delaware corporation (â€œenGene USAâ€), and each of their Subsidiaries (collectively referred to as, jointly and severally, the â€œBorrowerâ€), the several banks and other financial institutions or entities from time to time parties to the Existing Loan Agreement (and collectively referred to as the â€œLendersâ€) that are party hereto and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent, collateral agent and hypothecary representative for itself and the Lenders (in such capacities, the â€œAgentâ€). A.Borrower, Lenders and Agent are parties to that certain Amended and Restated Loan and Security Agreement, dated as of December 22, 2023 (as amended, restated, amended and restated, supplemented or otherwise modified from time to time to date, the â€œExisting Loan Agreementâ€ and the Existing Loan

Agreement, as amended by this Amendment, the â€œAmended Loan Agreementâ€). Borrower, Lenders and Agent have agreed to certain amendments to the Existing Loan Agreement upon the terms and conditions more fully set forth herein. SECTION 1Definitions; Interpretation. (a)Defined Terms. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Amended Loan Agreement. (b)Rules of Construction. The rules of construction that appear in Section 1.3 of the Amended Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference. SECTION 2Amendments to the Existing Loan Agreement. (a)The Existing Loan Agreement shall be amended as follows effective as of the date hereof (except as otherwise noted): (i)The following defined terms are hereby added, in appropriate alphabetical order, or amended and restated, as applicable, in Section 1.1 of the Existing Loan Agreement, as set forth below: â€œâ€œFirst Amendmentâ€ means that certain First Amendment to Amended and Restated Loan and Security Agreement, dated as of the First Amendment Effective Date, by and among Borrower, Lenders, and Agent. â€œFirst Amendment Effective Dateâ€ means December 18, 2024.â€ (ii)Sections 2.2(a)(ii) and 2.2(a)(iii) of the Existing Loan Agreement is hereby amended and restated to read as follows: â€œ(ii) Tranche 2. Subject to the terms and conditions of this Agreement and subject to the achievement of the Interim Milestone, prior to the First Amendment Effective Date, Borrower may request and each Lender shall severally (and not jointly) make, in an amount not to exceed its respective Tranche 2 Commitment, an additional Term Loan Advance in an aggregate amount up to DOCPROPERTY DOCXDOCID DMS=IManage Format=<>.<> PRESERVELOCATION 1612278539.2 Â Seven Million Five Hundred Thousand Dollars ($7,500,000) (the â€œTranche 2 Advanceâ€); provided that the parties hereto agree that the Term Commitments in respect of the Tranche 2 Commitment shall be immediately reduced to Zero Dollars ($0.00) as of the First Amendment Effective Date. (iii) Tranche 3. Subject to the terms and conditions of this Agreement, Borrower may request and the Lenders shall severally (and not jointly) make in each case, continuing through the Amortization Date and conditioned on approval by Lendersâ€™ investment committee in its sole and unfettered discretion, one or more additional Term Loan Advances in minimum increments of Five Million Dollars ($5,000,000) (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(a)(iii)) in an aggregate principal amount up to (x) prior to the First Amendment Effective Date, Twenty Million Dollars ($20,000,000) and (y) from and after the First Amendment Effective Date, Twenty-Seven Million Five Hundred Dollars ($27,500,000) (the â€œTranche 3 Advanceâ€).â€ (iii)Section 7.1 of the Existing Loan Agreement is hereby amended by amending the penultimate paragraph thereof in its entirety and replacing it with the following: â€œThe executed Compliance Certificate, and all Financial Statements required to be delivered pursuant to clauses (a), (b), (c), (d) and (f) shall be sent per instructions (i) specified in Addendum 5 or (ii) otherwise provided by Agent to Borrower via written notice from time to time.â€ (iv)Sections 11.2(a) and 11.2(b) of the Existing Loan Agreement are hereby amended and restated to read as follows: â€œ(a) If to Agent: HERCULES CAPITAL, INC. [***] (b) If to the Lenders: HERCULES CAPITAL, INC. [***] (v)A new Addendum 5 to the Existing Loan Agreement is hereby inserted immediately following Addendum 4 to the Existing Loan Agreement as set forth on Addendum 5 attached hereto. (vi)Schedule 1.1 of the Existing Loan Agreement is hereby replaced with Schedule 1.1 attached hereto. (b)References Within Amended Loan Agreement. Each reference in the Amended Loan Agreement to â€œthis Agreementâ€ and the words â€œhereof,â€ â€œherein,â€ â€œhereunder,â€ or words of like import, shall mean and be a reference to the Amended Loan Agreement. This Amendment shall be a Loan Document. Any failure by Borrower to perform any obligation under this Amendment shall constitute an Event of Default under the Amended Loan Agreement. SECTION 3Conditions to Effectiveness. The effectiveness of this Amendment shall be subject to satisfaction of each of the following conditions precedent: (a)Agent shall have received this Amendment, executed by Agent, Lenders, and Borrower; (b)immediately after giving effect to this Amendment, the representations and warranties contained in Section 4 hereof shall be true and correct on and as of the First Amendment Effective Date as though made on and as of such date; and 2 Â (c)there exist no Events of Default or events that, with the passage of time, could result in an Event of Default. SECTION 4Representations and Warranties. To induce Agent and Lenders to enter into this Amendment, Borrower hereby confirms, as of the date hereof and immediately after giving effect to this Amendment, (a) that the representations and warranties made by it in Section 5 of the Amended Loan Agreement and in the other Loan Documents are true and correct in all material respects (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date); provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and (b) that there has not been and there does not exist a Material Adverse Effect. SECTION 5Miscellaneous. (a)Loan Documents Otherwise Not Affected; Reaffirmation. Except as expressly amended pursuant hereto or referenced herein, the Existing Loan Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lendersâ€™ and Agentâ€™s execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. Borrower hereby reaffirms the security interest granted pursuant to the Loan Documents and hereby reaffirms that such grant of security in the Collateral granted as of the Closing Date continues without novation and secures all Secured Obligations under the Amended Loan Agreement and the other Loan Documents. Borrower acknowledges and agrees that it does not have any defense, set-off, counterclaim or challenge against the payment of any sums owing under the Existing Loan Agreement and the other Loan Documents, or the enforcement of any of the terms or conditions thereof. (b)Conditions. For purposes of determining compliance with the conditions specified in Section 3 hereof, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the date hereof specifying its objection thereto. (c)Release. In consideration of the agreements of Agent and Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors and assigns, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the â€œReleaseesâ€ and individually as a â€œReleaseeâ€), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Existing Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto (collectively, the â€œReleased Claimsâ€). Borrower waives the provisions of California Civil Code section 1542, which states: A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party. 3 Â Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above. The provisions of this section shall survive payment in full of the Secured Obligations, full performance of all the terms of this Amendment and the other Loan Documents. In addition to the release contained above, and not in limitation thereof, Borrower hereby agrees that it will never prosecute, nor voluntarily aid in the prosecution of, any action or proceeding relating to the Released Claims, whether by claim, counterclaim or otherwise. If, and to the extent that, any of the Released Claims are, for any reason whatsoever, not fully, finally and forever released and discharged pursuant to the terms above, Borrower hereby absolutely and unconditionally grants, sells, bargains, transfers, assigns and conveys to Agent all of the Released Claims and any proceeds, settlements and distributions relating thereto. (d)No Reliance. Borrower hereby acknowledges and confirms to Agent and Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person. (e)Binding Effect. This Amendment binds and is for the benefit of the successors and permitted assigns of each party. (f)Governing Law. This Amendment and the other Loan Documents shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction. (g)Complete Agreement; Amendments. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents. (h)Severability of Provisions. Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision. (i)Counterparts. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof. (j)Electronic Execution of Certain Other Documents. The words â€œexecution,â€ â€œexecuteâ€, â€œsigned,â€ â€œsignature,â€ and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the California Uniform Electronic Transaction Act, or any other similar state laws based on the Uniform Electronic Transactions Act. (k)Inconsistencies. To the extent of any inconsistency between the terms and conditions of this Amendment and the terms and conditions of the Existing Loan Agreement and the other Loan Documents, the terms and conditions of this Amendment shall prevail. [remainder of page intentionally left blank] 4 Â Â 5 Â IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written. BORROWER: ENGENE HOLDINGS INC.Â Signature: /s/ Ryan Daws____________ Print Name: Ryan Daws Title: Chief Financial Officer Â ENGENE INC.Â Signature: /s/ Ryan Daws____________ Print Name: Ryan Daws Title: Chief Financial Officer Â ENGENE usa INC.Â Signature: /s/ Ryan Daws____________ Print Name: Ryan Daws Title: Chief Financial Officer [Signature Page to First Amendment to Amended and Restated Loan and Security Agreement] DOCPROPERTY DOCXDOCID DMS=IManage Format=<>.<> PRESERVELOCATION 1612278539.2 Â AGENT: HERCULES CAPITAL, INC. Signature: /s/ Prentis Robinson III______ Print Name: Prentis Robinson III Title: Associate General Counsel Â LENDERS: HERCULES CAPITAL, INC. Signature: /s/ Prentis Robinson III______ Print Name: Prentis Robinson III Title: Associate General Counsel Â HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P. By: Hercules Adviser LLC, its Investment Adviser Signature: /s/ Prentis Robinson III______ Print Name: Prentis Robinson III Title: Authorized Signatory Â Â Â [Signature Page to First Amendment to Amended and Restated Loan and Security Agreement] Â ADDENDUM 5 to LOAN AND SECURITY AGREEMENT Delivery Instructions The Compliance Certificate shall be uploaded and executed via [***]1. All other financial reports required to be furnished to Agent pursuant to Section 7.1 shall be submitted via [***]. The Compliance Certificate and other financial reports required to be furnished to Agent pursuant to Section 7.1 may be sent to [***] with a copy to [***], should access to [***] be temporarily unavailable. 1 All references to [***] shall be interpreted as the Portfolio Management Software currently in use by Agent. [***] can be reached at the following URL: [***]Â Â SCHEDULE 1.1 COMMITMENTS Â LENDERS TRANCHE 1 COMMITMENT TRANCHE 2 COMMITMENT TRANCHE 3 COMMITMENT TOTAL COMMITMENT Hercules Capital, Inc. $15,750,000 $0 $27,500,000 $43,250000 Hercules Private Global Venture Growth Fund I L.P. $6,750,000 $0 $0 $6,750,000 TOTAL COMMITMENTS $22,500,000 $0 $27,500,000 $50,000,000 Â Â EX-19.1 6 engn-ex19_1.htm EX-19.1 EX-19.1 Exhibit 19.1 ENGENE HOLDINGS INC. INSIDER TRADING POLICY Adopted November 22, 2023, as amended September 18, 2024 Â Â This insider trading policy (the â€œInsider Trading Policyâ€) has been adopted by the board of directors (the â€œBoardâ€) of enGene Holdings Inc. (the â€œCompanyâ€). â€¢PURPOSE The Company is a publicly traded company and is subject to securities laws in the United States and Canada. The Board has implemented this Insider Trading Policy to prevent insider trading and tipping violations by people who have access to Material Information (as defined below) that is not available to the general public. Any violation of this Insider Trading Policy or insider trading law can result in disciplinary action, including termination of employment with the Company, as well as legal consequences such as fines or imprisonment. Preventing insider trading and tipping keeps markets fair and ensures all investors have access to the same information. It is the personal responsibility of each Company director, officer, employee and other personnel that the Company may determine should be subject to this Insider Trading Policy, such as contractors or consultants (â€œOther Personnelâ€) to comply with this Insider Trading Policy and all applicable securities laws when trading in the Companyâ€™s securities or the securities of companies with which the Company does business. If there is ever any conflict between this Insider Trading Policy and applicable securities laws, only the sections of this policy permitted by applicable law or regulation will apply. â€¢APPLICATION Who does this Insider Trading Policy apply to? This Insider Trading Policy applies to: â€¢all Company directors, officers, employees and Other Personnel (for the purpose of this policy, â€œinsidersâ€); â€¢any person or entity (such as a corporation, trust, partnership, investment fund, etc.) an insider controls, exercises substantial influence over, serves as a trustee or in a similar fiduciary capacity of or is otherwise involved with, in connection with securities trading or investment decisions; and â€¢an insiderâ€™s spouse, partner, parents, children, dependents and other family members or roommates (collectively, â€œCovered Personsâ€). Â 1 Â Â Notwithstanding the foregoing, this Insider Trading Policy shall not apply to any entity that engages in the investment of securities in the ordinary course of business (e.g. investment fund or partnership) if such an entity has established its own insider trading controls and procedures in compliance with applicable securities laws. Â What type of transactions does this Insider Trading Policy cover? This Insider Trading Policy applies to all transactions in the Companyâ€™s securities, including the Companyâ€™s common shares, or any debt instruments, or puts, calls, options or other rights to purchase or sell the Companyâ€™s securities, or any security that is in any way tied to the Companyâ€™s share price (collectively, â€œCompany Securitiesâ€). Every Covered Person is prohibited from insider trading or tipping as relates to Company Securities. This Insider Trading Policy also applies to non-public Material Information relating to other companies with which the Company does business, including partners and customers, as well as potential merger or acquisition candidates. For the purpose of this Insider Trading Policy, information about these companies should be treated in the same way as information directly related to the Company. Every Company insider is prohibited from speculative or indirect trading in Company Securities â€“such as short sales, trading in puts, calls or options (not stock options granted by the Company) â€“or similar rights or obligations to buy or sell Company Securities, or the purchase of Company Securities with the intention of quickly reselling them. Company insiders may not buy Company Securities on margin, and are prohibited from purchasing financial instruments designed to hedge or offset a decrease in the market value of Company Securities. Insiders are strongly discouraged from using Company Securities as collateral for loans or in margin accounts. A violation of insider trading and tipping laws can result in civil or criminal penalties not only for the person who trades in possession of non-public Material Information, but also for anyone who tips or otherwise aids the person doing the trading. â€¢INSIDER TRADING It is illegal for anyone to buy or sell shares or other securities, including the exercise of stock options or any other securities pursuant to any benefit plan or arrangement, of any reporting issuer (i.e. public company) at any time when a person is in possession of Material Information related to that issuer that has not yet been made publicly available. To do so would be insider trading. Â 2 Â â€¢TIPPING Subject to limited defenses, such as disclosure made â€œin the necessary course of businessâ€, it is illegal to share Material Information that has not yet been made public with another person (including friends and family members) because they may decide to buy or sell securities based on that information. It is illegal to make recommendations or express opinions to another person regarding trading in any securities (whether Company Securities or another issuerâ€™s) on the basis of non-public Material Information. To do so would be tipping. The â€œnecessary course of businessâ€ generally means sharing information that is reasonably necessary in the course of the Companyâ€™s business with: â€¢employees, officers and directors; â€¢partners on issues such as research and development; â€¢lenders, legal counsel, auditors, underwriters and financial or other professional advisors; â€¢parties to negotiations; â€¢government agencies and non-governmental regulators; or â€¢credit rating agencies (provided that the information is disclosed for the purpose of assisting the agency to formulate a credit rating and the agencyâ€™s ratings generally are or will be publicly available). If you are ever unsure of whether or not communications are reasonably necessary in the necessary course of business, speak to the Chief Financial Officer. â€¢MATERIAL INFORMATION Material Information means:

â€¢any fact that significantly affects, or would reasonably be expected to have a significant effect on, the market price or value of an issuerâ€™s securities; â€¢information if there is a substantial likelihood that a reasonable investor would consider it important in making an investment decision or information that could otherwise affect the decision of a reasonable investor; â€¢information that would significantly alter the total mix of information available to investors; â€¢material changes, meaning any change in the business, operations or capital of the Company that would reasonably be expected to have a significant effect on the market price or value of Company Securities; and â€¢if the Board or executive team has made a decision to implement a change â€“ even if the change has not yet occurred â€“ the decision itself would be Material Information. Â 3 Â Either good or bad information may be Material Information. Some examples of information that may be considered to be Material Information are listed in Appendix â€œAâ€ hereto. What does it mean for Material Information to be publicly available? Material Information about the Company should always be considered to be non-public unless the information has been widely distributed in a manner making it generally available to investors, such as when the Company has: (i) issued a press release or (ii) made a regulatory filing with provincial securities regulators or the U.S. Securities and Exchange Commission (â€œSECâ€) about the information, and a reasonable period of time has passed for the markets to react to the information and investors have had time to buy or sell based on the information. Material Information has to be distributed by the Company to be publicly available - the circulation of rumours, even if accurate and reported in the media (print, web, social), does not constitute effective public dissemination. â€¢BLACKOUT PERIODS In addition to the general prohibition against insider trading and tipping described above, the Company may, from time to time, impose blackout periods on some or all insiders, during which they cannot buy or sell Company Securities. If insiders receive a notice not to trade, they are prohibited from trading in Company Securities until they are notified by the Chief Financial Officer that the blackout period has ended. Insiders shall not advise others as the existence of the blackout period. Orders placed with a broker should be cancellable upon the start of any blackout period. Covered Persons are never permitted to trade with knowledge of any non-public Material Information, regardless of whether or not there is a blackout period in effect. Quarterly Blackout Periods No Covered Persons shall trade in Company Securities during the period commencing at 11:59 pm Eastern Time on the final day of the final month of each fiscal quarter and ending upon completion of one full trading day following the date of the public release of the Companyâ€™s interim or annual financial statements. â€¢CONSEQUENCES OF VIOLATION The consequences of insider trading or tipping can be severe and may include civil penalties, fines and criminal sanctions. Insiders who violate this Insider Trading Policy will also be subject to disciplinary action by the Company, up to and including possible termination of employment or other relationship with the Company. In addition to these penalties, persons sanctioned for violations of securities laws may be limited from engaging in other types of business in the future. Â 4 Â If an insider were even accused of securities law violations it would have very damaging effects on their reputation and the Companyâ€™s reputation. Insiders may also be liable for improper trading by any person to whom the insider has disclosed non-public Material Information or to whom the insider has made recommendations or expressed opinions as to trading in Company Securities. Securities regulators have imposed large penalties even when the disclosing person did not profit from the trading. Securities regulators use sophisticated electronic surveillance techniques to uncover insider trading. â€¢REPORTING INSIDERS SEDI Reporting. â€œReporting Insidersâ€ within the meaning of National Instrument 55-104 â€“ Insider Reporting Requirements and Exemptions (including members of the Board, executive officers and significant shareholders) are required under applicable Canadian securities legislation to report their trades of Company Securities on the System for Electronic Disclosure by Insiders, commonly known as â€œSEDIâ€ (www.sedi.ca) in Canada. These reports are required within 5 (five) days of the trade. In addition, a Reporting Insider is required to file an insider trading report within 10 (ten) days after becoming a Reporting Insider, disclosing such personâ€™s beneficial ownership of, or control or direction over Company Securities. Rule 144. In addition, Reporting Insiders who sell Company Securities in the United States through the NASDAQ must comply with the volume, manner of sale and notice requirements of Rule 144 under the U.S. Securities Act of 1933. Reporting Insiders who are considered â€œaffiliatesâ€ of the Company under U.S. securities laws by virtue of reasons other than being a member of the board of directors or officer (e.g. the Reporting Insider is also a significant shareholder) must comply with additional requirements under U.S. federal securities laws in connection with sales of Company Securities, even if such sales take place outside the United States, and should consult legal counsel in advance of such sales. Filings. Reporting Insiders are legally responsible for ensuring that they are in compliance with reporting requirements, however the Chief Financial Officer will, when asked, arrange to file the required insider reports with the securities regulatory authorities on behalf of the Reporting Insider. Such Reporting Insiders are responsible for ensuring the accuracy of any such reports. While the Company may assist a Reporting Insider to file required reports and forms and to comply with applicable resale restrictions, the Reporting Insider has the ultimate responsibility for complying with applicable securities laws in connection with his, her or its sale of Company Securities. Reporting Insiders are required to promptly provide a copy of any insider trading reports to the Chief Financial Officer so that the Company may update its records. Â 5 Â â€¢AUTOMATIC SECURITIES DISPOSITION PLANS An automatic securities disposition plan (â€œASDPâ€) is a plan established by an insider with a broker while the insider is not in possession of any non-public Material Information and not subject to a blackout period, to allow for exercises of options or dispositions in accordance with pre-arranged instructions, which can then occur even if the insider would not otherwise be allowed to trade. The Company may participate in the establishment of ASDPs in accordance with this Insider Trading Policy as long as an ASDP complies with all applicable Canadian and U.S. securities laws. â€¢LEGAL CAUTION This Insider Trading Policy is only a general framework and should be viewed as the minimum standard for compliance with insider trading laws. Every insider has the ultimate responsibility for complying with insider trading laws. Questions about the Insider Trading Policy may be directed to the Chief Financial Officer. The Board may, from time to time, permit departures from the terms hereof, either prospectively or retrospectively, and no provision contained herein is intended to give rise to civil liability to shareholders, competitors, employees or other persons, or to any other liability whatsoever. â€¢REVIEW OF POLICY The Board shall review this Policy on a periodic basis to determine whether the procedures established under this Policy operate effectively to prevent insider trading and tipping violations by people who have access to Material Information that is not available to the general public Â 6 Â APPENDIX â€œAâ€ The following are examples of the types of events or information that may be Material Information. This list is not exhaustive and is not a substitute for companies exercising their own judgment in making materiality determinations. In making materiality judgments, it is necessary to take into account a number of factors that cannot be captured in a single bright-line standard or test. Changes in Corporate Structure â€¢changes in share ownership that may affect control of the Company. â€¢major reorganizations, amalgamations or mergers. â€¢take-over bids, issuer bids or insider bids. Changes in Capital Structure â€¢the public or private sale of additional securities. â€¢planned repurchases or redemptions of securities. â€¢planned splits of shares or offerings of warrants or rights to buy shares. â€¢any share consolidation, share exchange or stock dividend. â€¢the possible initiation of a proxy fight. â€¢material modifications to rights of security holders. Changes in Financial Results â€¢a significant increase or decrease in earnings. â€¢unexpected changes in the financial results for any periods. â€¢shifts in financial circumstances, such as cash flow reductions, major asset write-offs or write- downs. â€¢changes in the value or composition of the Companyâ€™s assets. â€¢any material change in the Companyâ€™s accounting policy. Changes in Business and Operations â€¢any development that affects the Companyâ€™s research, products or markets. â€¢a significant change in capital investment plans or corporate objectives. â€¢product and research developments, clinical results, approval and other regulatory actions. Â 7 Â â€¢government inspections. â€¢significant new contracts, products or patents or significant losses of contracts or business. â€¢changes to the board of directors or executive management. â€¢the commencement of, or developments in, material legal proceedings or regulatory matters. â€¢waivers of corporate ethics and conduct rules for directors, officers and other key employees. â€¢any notice that reliance on a prior audit is no longer permissible. â€¢de-listing of the Companyâ€™s securities or their movement from one quotation system or exchange to another. â€¢a cybersecurity incident or risk that may adversely impact the Companyâ€™s business, reputation or share value. Â 8 Â Transactions â€¢significant acquisitions or dispositions of assets, property or joint venture interest. â€¢acquisitions of other companies, including a take-over bid, or merger with, another company. â€¢partnerships and collaborations; research or development agreements; in-licensing or out- licensing of products or product candidates; marketing, co-marketing and co-promotion agreements; acquisitions or other business combinations and strategic equity investments. Changes in Credit Arrangements â€¢the borrowing or lending of a significant amount of money. â€¢any mortgaging or encumbering of the Companyâ€™s assets. â€¢defaults under debt obligations, agreements to restructure debt or planned enforcement procedures by a bank or any other creditors. â€¢changes in rating agency decisions. â€¢significant new credit arrangements. Â 9 EX-23.1 7 engn-ex23_1.htm EX-23.1 EX-23.1 Â Consent of Independent Registered Public Accounting Firm We consent to the incorporation by reference in the registration statements (No. 333-283201 and No. 333-283202) on Form S-3 and registration statement (No. 333-277378) on Form S-8 of our report dated December 19, 2024, with respect to the consolidated balance sheets as of October 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred shares and shareholdersâ€™ equity (deficit) and cash flows for the years then ended, and the related notes, of enGene Holdings Inc. /s/ KPMG LLP December 19, 2024 MontrÃ©al, Canada Â Â Â EX-31.1 8 engn-ex31_1.htm EX-31.1 EX-31.1 Â Exhibit 31.1 CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002 I, Ronald H. W. Cooper, certify that: (1)I have reviewed this Annual Report on Form 10-K of enGene Holdings Inc.; (2)Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; (3)Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; (4)The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have: (a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; (b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; (c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and (d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and (5)The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions): (a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and (b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting. Date: December 19, 2024 By: /s/ Ronald H. W. Cooper Ronald H. W. Cooper Chief Executive Officer Â EX-31.2 9 engn-ex31_2.htm EX-31.2 EX-31.2 Â Exhibit 31.2 CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002 I, Ryan Daws, certify that: (1)I have reviewed this Annual Report on Form 10-K of enGene Holdings Inc.; (2)Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; (3)Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; (4)The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have: (a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; (b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; (c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and (d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and (5)The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions): (a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and (b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting. Â Â Date: December 19, 2024 By: /s/ Ryan Daws Ryan Daws Chief Financial Officer Â Â EX-32.1 10 engn-ex32_1.htm EX-32.1 EX-32.1 Â Â Exhibit 32.1 CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 In connection with the Annual Report of enGene Holdings Inc. (the â€œCompanyâ€) on Form 10-K for the period ending October 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the â€œReportâ€), I certify, pursuant to 18 U.S.C. Â§ 1350, as adopted pursuant to Â§ 906 of the Sarbanes-Oxley Act of 2002, that: (1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2)The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company. Â Date: December 19, 2024 By: /s/ Ronald H. W. Cooper Ronald H. W. Cooper Chief Executive Officer Â Â EX-32.2 11 engn-ex32_2.htm EX-32.2 EX-32.2 Â Exhibit 32.2 CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 In connection with the Annual Report of enGene Holdings Inc. (the â€œCompanyâ€) on Form 10-K for the period ending October 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the â€œReportâ€), I certify, pursuant to 18 U.S.C. Â§ 1350, as adopted pursuant to Â§ 906 of the Sarbanes-Oxley Act of 2002, that: (1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2)The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company. Â Date: December 19, 2024 Â By: /s/ Ryan Daws Â Â Â Ryan Daws Â Â Â Chief Financial Officer Â Â EX-97.1 12 engn-ex97_1.htm EX-97.1 EX-97.1 Â ENGENE HOLDINGS INC. COMPENSATION RECOUPMENT POLICY The Board of Directors (the â€œBoardâ€) of enGene Holdings Inc. (the â€œCompanyâ€) has adopted this Compensation Recoupment Policy (this â€œPolicyâ€) in order to implement a mandatory clawback policy in the event of a Restatement in compliance with the Applicable Rules (each, as defined below) to be administered by the Boardâ€™s Compensation Committee (the â€œCommitteeâ€). I.Defined Terms a.â€œApplicable Rulesâ€ means Section 10D of the Exchange Act and Rule 10D-1 promulgated thereunder, Nasdaq Listing Rule 5608, and any other applicable national stock exchange rules that the Company is or may become subject to. b.â€œClawback Compensationâ€ means Incentive-Based Compensation determined to be subject to repayment pursuant to this Policy. c.â€œClawback Eventâ€ means a required recoupment of Incentive-Based Compensation in the event of a Restatement. d.â€œCovered Officerâ€ means any person currently or formerly designated by the Board as an â€œofficerâ€ for purposes of Section 16 of the Exchange Act and the related promulgated rules, or as otherwise determined by the Board in accordance with the definition of executive officer as set forth in the Applicable Rules. e.â€œEffective Dateâ€ means October 2, 2023. f.â€œEquity Awardâ€ means any equity or equity-based award granted to a Covered Officer, regardless of whether such award is subject to time-vesting or performance-vesting conditions. g.â€œExchange Actâ€ means the Securities Exchange Act of 1934, as amended. h.â€œFinancial Reporting Measuresâ€ mean (i) measures that are determined and presented in accordance with the accounting principles used in preparing the Companyâ€™s financial statements, and any measures that are derived wholly or in part from such measures, (ii) the

Companyâ€™s stock price, and (iii) total shareholder return in respect of the Company. A â€œFinancial Reporting Measureâ€ need not be presented within the financial statements or included in a filing with the SEC. i.â€œIncentive-Based Compensationâ€ means any compensation that is granted, earned, or vested, based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation does not include, among other forms of compensation, equity awards that vest exclusively upon completion of a specified employment period, without any performance condition, and bonus awards that are discretionary or based on subjective goals or goals unrelated to Financial Reporting Measures. j."Nasdaqâ€ means The Nasdaq Stock Market LLC. Â Â k.â€œReceivedâ€ â€“ Incentive-Based Compensation is deemed â€œReceivedâ€ for the purposes of this Policy in the Companyâ€™s fiscal period during which the Financial Reporting Measure applicable to the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period. l.â€œRecovery Periodâ€ means the three completed fiscal years immediately preceding the date on which the Company is required to prepare a Restatement, which date is the earlier of (i) the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement or (ii) a date that a court, regulator, or other legally authorized body directs the Company to prepare a Restatement. m.â€œRegulatorsâ€ means, as applicable, the SEC and Nasdaq. n.â€œRestatementâ€ means an accounting restatement of the Companyâ€™s financial statements that the Company is required to prepare due to the Companyâ€™s material noncompliance with any financial reporting requirement under applicable U.S. federal securities laws, including any required accounting restatement to correct an error in previously issued financial statements that (i) is material to the previously issued financial statements, or (ii) would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. o.â€œSECâ€ means the U.S. Securities and Exchange Commission. II.Administration This Policy shall be administered by the Committee, which shall make all determinations with respect to this Policy, provided that this Policy shall be interpreted in a manner consistent with the requirements of the Applicable Rules. III.Recovery on a Restatement In the event that the Company is required to prepare a Restatement, the Company shall reasonably promptly recover the amount, as calculated pursuant to this Section III, of any erroneously awarded Incentive-Based Compensation that is Received by a Covered Officer during the Recovery Period. The amount of erroneously Received Incentive-Based Compensation will be the excess of the amount of Incentive-Based Compensation that is Received by the Covered Officer (whether in cash or shares) based on the erroneous data in the original financial statements over the amount of Incentive-Based Compensation (whether in cash or in shares) that would have been Received by the Covered Officer had such Incentive-Based Compensation been based on the restated results, without respect to any tax liabilities incurred or paid by the Covered Officer. Without limiting the foregoing, for Incentive-Based Compensation based on the Companyâ€™s stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Restatement, (a) the amount shall be based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received and (b) the Company shall maintain documentation of the determination of that reasonable estimate and provide such estimate to Nasdaq. Â 2 Â IV.Coverage and Application This Policy covers all persons who are Covered Officers at any time during the Recovery Period for which Incentive-Based Compensation is Received. Incentive-Based Compensation shall not be recovered under this Policy to the extent it is Received by any person before the date the person served as a Covered Officer. Subsequent changes in a Covered Officerâ€™s employment status, including retirement or termination of employment, do not affect the Companyâ€™s right or obligation to recover compensation pursuant to this Policy. For the avoidance of doubt, this Policy shall apply to Incentive-Based Compensation that is Received by any Covered Officer on or after the Effective Date that resulted from attainment of a Financial Reporting Measure based on or derived from financial information for any fiscal period ending on or after the Effective Date. V.Exceptions to Policy No recovery of Incentive-Based Compensation shall be required if any of the following conditions are met and the Committee determines that, on such basis, recovery would be impracticable: a.the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered; provided that prior to making a determination that it would be impracticable to recover any Incentive-Based Compensation based on the expense of enforcement, the Company shall (i) have made a reasonable attempt to recover the Incentive-Based Compensation, (ii) have documented such reasonable attempt(s) to recover, and (iii) provide this documentation to Nasdaq; b.recovery would violate home country law where that law was adopted prior to November 28, 2022; provided that prior to making a determination that it would be impracticable to recover any Incentive-Based Compensation based on violation of home country law, the Company shall (i) have obtained an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such violation, and (ii) provide a copy of such opinion to Nasdaq; or c.recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and U.S. Treasury regulations promulgated thereunder. VI.Public Disclosure The Company shall make all required disclosures and filings with the Regulators with respect to this Policy in accordance with the requirements of the Applicable Rules and any other requirements applicable to the Company, including any disclosures required in connection with SEC filings. VII.[Reserved.] VIII.Methods of Recovery Â 3 Â In the event of a Clawback Event, subject to applicable law, the Committee may take any such actions as it deems necessary or appropriate to recover Clawback Compensation. These actions may include, without limitation: a.the cancellation of any Clawback Compensation in the form of vested or unvested equity or equity-based awards that have not been distributed or otherwise settled prior to the date of determination; b.the recovery of any Clawback Compensation that was previously paid to the Covered Officer; c.the recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any Clawback Compensation in the form of equity or equity-based awards; d.the offset, withholding, or elimination of any compensation that could be paid or awarded to the Covered Officer after the date of determination; e.the recoupment of any amount in respect of Clawback Compensation contributed to a plan that takes into account Clawback Compensation (excluding certain tax-qualified plans, but including long-term disability, life insurance, and supplemental executive retirement plans) and any earnings accrued to date on that notional amount; and f.the taking of any other remedial and recovery action permitted by law, as determined by the Committee. In addition, the Committee may authorize legal action for breach of fiduciary duty or other violation of law and take such other actions to enforce the Covered Officerâ€™s obligations to the Company as the Committee deems appropriate. IX.No Indemnification The Company shall not indemnify any current or former Covered Officer against the loss of erroneously awarded compensation, and shall not pay or reimburse any Covered Officer for premiums incurred or paid for any insurance policy to fund such Covered Officerâ€™s potential recovery obligations. X.No Substitution of Rights; Non-Exhaustive Rights Any right of recoupment under this Policy is in addition to, and not in lieu of, (a) any other remedies or rights of recoupment that may be available to the Company pursuant to any incentive plan of the Company or any of its subsidiaries or affiliates or the terms of any similar policy or provision in any employment agreement, compensation agreement or arrangement, or similar agreement or (b) any other legal remedies available to the Company. In addition to recovery of compensation as provided for in this Policy, the Company may take any and all other actions as it deems necessary, appropriate, and in the Companyâ€™s best interest in connection with a Clawback Event, including termination of a Covered Officerâ€™s employment and initiation of legal action against a Covered Officer, and nothing in this Policy limits the Companyâ€™s rights to take any such action or other appropriate actions. XI.Amendment Â 4 Â The Board, based upon the recommendation of the Committee, may amend this Policy at any time for any reason, subject to any limitations under the Applicable Rules. XII.Effective Date This Policy shall be effective as of the Effective Date. For the avoidance of doubt, the terms of this Policy shall apply to any Incentive-Based Compensation Received by any Covered Officer on or after the Effective Date, even if such compensation was approved, awarded, granted, or paid to such Covered Officer prior to the Effective Date. Subject to applicable law, the Committee may effect recovery under this Policy from any amount of compensation approved, awarded, granted, payable, or paid to any Covered Officer prior to, on, or after the Effective Date. Â 5 Â Compensation Recoupment Policy Acknowledgement Â I, the undersigned, agree and acknowledge that I am fully bound by, and subject to, all of the terms and conditions of the Compensation Recoupment Policy (as it may be amended, restated, supplemented, or otherwise modified from time to time, the â€œPolicyâ€) of enGene Holdings Inc. (the â€œCompanyâ€). I further acknowledge that any right of recoupment under the Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any employment agreement, equity award agreement, equity incentive plan, cash incentive plan or similar agreement, plan, or policy and any other legal remedies available to the Company. In the event it is determined by the Companyâ€™s Board of Directors or its designee that any amounts granted, awarded, earned, or paid to me must be forfeited or reimbursed to the Company, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. Â Â By: [Name] [Title] Â Â Date: Â Â

GRAPHIC 13 img84713370_0.jpg GRAPHIC begin 644 img84713370_0.jpg M_]C_X 02D9)1@ ! @ 0 ! #_VP!# @&!@<&!0@'!P<)"0@*#!0-# L+ M#!D2$P\4'1H?'AT:'!P@)"XG("(L(QP<*#7J#A(6&AXB)BI*3E)66EYB9FJ*CI*6FIZBIJK*SM+6VM[BYNL+#Q,7& MQ\C)RM+3U-76U]C9VN'BX^3EYN?HZ>KQ\O/T]?;W^/GZ_\0 'P$ P$! 0$! M 0$! 0 $" P0%!@<("0H+_\0 M1$ @$"! 0#! <%! 0 0)W $" M Q$$!2$Q!A)!40=A<1,B,H$(%$*1H;'!"2,4O 58G+1"A8D-.$E\1<8&1HF M)R@I*C4V-S@Y.D-$149'2$E*4U155E=865IC9&5F9VAI:G-T=79W>'EZ@H.$ MA8:'B(F*DI.4E9:7F)F:HJ.DI::GJ*FJLK.TM;:WN+FZPL/$Q<;'R,G*TM/4 MU=;7V-G:XN/DY>;GZ.GJ\O/T]?;W^/GZ_]H # ,! (1 Q$ /P#W^BBB@ HH MHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB M@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** M"BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH * M*** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HH MHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB M@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** M"BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH * M*** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HH MHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB M@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** M"BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH * M*** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HH MHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB M@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** "BBB@ HHHH **** M"BBB@ HHHH **** "BBB@ HHHH ***S]:M?/LMK2(R.>Y] /GSW2!XQ;_\LB^" V<\#(S[5].T %%%% !1 M6!XS\56_@SPM=:Y4P_O4DC";>#(7!^8G. M1C'3%>LT %%%>6_%*#XDW6LZ;#X,,L=B8CYTD,L:'S"W\6XYP!CIZF@#U*BH M;-)XK&WCN91+<+&JRR 8#L!R?Q-34 %%%% !117(_$+QY:_#_1(-1N+-[QYY MQ#"'CA#T)))(/ QZ=Q0!UU%9/AG6_P#A(_#6GZR+9[87D0E$+MN*@].>_K^- M:U !1110 45D>*M4.B>$M7U,-M>ULY94/^T%%.W]<5Y5^SS=:OJEEKNHZGJ=[M>1F6.&(7$[2 , S,1N)Y^9: /;**P?&GB ^%O!NJ:TB(\EK"6C5_NER0J@^V MXBO"/#'QU@QU\6)\\]I+G)#@'Z>W"/M2!(;LXJF)A&^HIBXUE]RF&VRT!E%_JP\ MVZ.[/'M!#X.3PAD6:KY\H!<#%'O.R[TH7HPE?P7]UKY
NJ:E!>HBH5)SW1YH,W%%-Q
MJS>%?^BOVHPMT!XB/V2UNSX6V^@*RT68\ MV@CE)J<+Y$#EJY>4;[WU<:2+OT"V-G\Q2>DOSM7\ZS>'S(]X2MQ MFIBD4(5&F(<-S)+[VCN.]KN-?'I>OQPL3]27+E<50>/VP7#C1?;^#M/1T4OK MD]_IF8SR24>)0!>&K]7?Z]R-&@MP9L8J3U5:J@!<+3N\OF\>VWE^X7PN,XE(?5>/UH.2)*?6#&\H?8:R MQ&/4PXL\"R!C<:M+R.2@0?D#S9J"IG;[\8UX[B)]E;F-J_R6G(^RO\#FQL/1 M2E9S(Y?F>:\R63KI?$$@V^)6;9/B8<#3D-$1P(")?5O5BW"C^:0$_+61)^2@ M6]7;7!F#\JZF.A#L.KM8=F?:#'+@<;DF1!"G0VDQPV5ACO@S:[?1;]9I&!"?> MN^KYF1;J;7VOHM*^TK.5*E>@_+%[EXB6J#/JQ@71&@GI]*!>B0Z+7*O0:4'0 MIIB#/CUOA.A"UHUB[=9PR!.@>>V#L+[O5J!N/0,=0MU.4%S[4MC*?DL:1PO9 MSXG,_:Q<[KK]EPVZ2%9*G+0)-H1?X3!7L5A=RV@Y M1TAK2:M00J1N\1&4G'6G5'2C+-[^.\6FUMIPW@Y4;)^_UG.[.J8;46,T8PV(K1FU%L@ MPB/?^=97(QR_7%[MGMC8OLC+68T%JBT?QX:.^K4U1&[-WY(LM+ZSSXDAT12OZ4A_[5\'9];_SHJ6MO[Q'';K]84"\R%/>\J'Z%VY 55+?_NI?I7V=3> MWU7 MHY.P_"6X6%6T38FS6TS_^7/&U[TX2<:7]EXPZ16R8@K=6'<8.S=FI"]4D/O6UIQ8=#(M<;4/;[.D47[+C"[H/IQ[A^_^0?HVH!Y-KW3,S_:'?WAP.=6\L0H!>^(S\ M%\F#IYH&>1]Y\9?53V*)/!6.W7T0$#ZT-JSF6LA 4'54;T'J/\MV4.^MXO/ MJ]@EO1:2>)J%4'!?>)5D/SOYS4?4W'IWGO+:Y!IN!EVPD$K MHY,!S2]U&<2]MQ?-:4U?>/;5!\,$CWQ/ZO4;\UGH7U>@'>Y4SL>5BV=Y7+C;XNU^]A,=>YXQ.1]B_63Y,5:$8A%#;$?P%UOS^6\P/>GNW)$G1U%>/(/4[5BP^D;M\X6ZAUNX)F&7H6!AL];0(:(VW+A=;,^6K@ZK4$4*3\]1%,>IX&C3_S+B.$2_P^"X)2/]P4VA&OZ:>/[>I6/#;]]<%0KO38WVW6C%5 M7PSQ?IO!\$!*]P[B3^D4PZBGQ-T/18G$NT=7M3DPO4S4^ MJ/7X*'6V_W4/-;0ML@&ZQO.-Z8(T!L]XZNT:[A6DO-.B!6?"%KN[S!8I"]'X<")MT)3(V"^5?UZ$B%V?:*5>S3"7ZQO9X?HIJXB6LJSD]>KQG1^L&+YV18L64@N//%(';)ZAD4ZBCXN+AQ=L(0Z*0UW
MK]IZ@!Y9=-$<:1#[B[\T;XE37"S:X!$;=*_$G3#2J]WI#7_9LT9#O"3#%U(')#1G:"$C/+1%*(IE_YUQK9=R9L]6J'D[=K)1M>DU&XTV1.EQS!_WS_TA0/9#'1;,GO>EHK^AK>!6.4CLQRNZJ=8IH-#$-8V;U&FFNR2;4JLYGOR/0ZX?[>HI&BEL5N=C%G5L\/&>TY*O7,%^%5OGW?84XW+BCN=-L73]EUC7J!.0KQN4B-XM$J;.DVG:3RI*M+ALD:T=9N]G)A+
T.ET+2ZS^T0!D+?.QDD)5>M_GH0(E^CW[8GLC3>46=F6CGF>+=>0G5!)]2K8U92>J-QHX@HPI;2@S+_42QW,CS.B'>"36G5L^\OK0R=+KU*&=:VUG-@7]&QXU;,C=9U"CX4JCB_Q0U+ M@.5VV+X.S0H.SMKWDOQ$X&R:%P]I+9T,$$RE=S5#=!UV&:8K:3"8#'L!\ZD3Y8.]E[5AJ@W[R8 M:1JU=>!/(>U2R8])X01LK:JMO!GVG-A7'X,RUUMS^HPW_5W^_W4SM_?>CA=8I>+T/U[D;O\GVB(H,Z)Q[ZA$U-%X;JYFUE=O)VVD/ECZ9^7PGZRK0GV/T6)WE2V]5P=K@OO0.C]H[8;B]$G;.0]A0=_BS!?\?(?@?/#S3QK>5FIOS#8$-C#4#G7\UY^>02.S96>Q1O#3M4+#Z\'_1'F*6?_G2/?*R&3+_87FCE+'+6#E7)[/=NSLT>#TC%I;6L+OC*_#$:&V/5Q];NKZ=Y0P2[VIX50_MH[X54S"4:RM)YU^L*\I87BH@NTIB/2D@C0M[9U:5YHM1RKF=JUA2EX[9I-IJL4(3RC52BN*6_N;LN@,M'4V,1&@>[+!?+_Z]F@\!JHJP6];9X$A'"QP7FGRP\E'@7QRG4UNI8:TH1&I<=/=4N8A)M"ASE#7;6+L8WC<\,$9Y;E9=1DDZUM>[KLEF;]/!)VKH=/Q[:XOL9)X:8E2UDJZJYE:OD,!VIRNY27-U[I?$O3T0VW.M9!MY)3BLK>TNIUR=K!K>$Y&_[2U6P9^'5L[,A9!(\Q'*'3W^[5!)^&V9#PM)6ZMW:=&6IJJ]I-8ERQQR[S2F5JDY.];=;Y]FOI6;@/&2J%U+]:\!OAA?VXSJ7*YJ4WH3IP*4*VB3;Y2LOY8NMZ<#9\L.1SMZV2HFU#YG0F7TN]=1KSHS^0GM,\\],H0!H4TU6\IOY,7TN:1L/CXQG=1M;KBRS9Z\DX1"XC;&U\9Z-(7.!S;(0/R2VUJQKTKEJGF;]UX-IL*3;!1@FXY39H=/B-]S2/>SJ;5M*^:97Q/!8L%69[V^"S"
[Transcription cut off: the uuencoded data after this point could not be written out reliably.]

~~<47/%?S%4ZQOHW>9&N%?E J^2[2TMLQ14] MQ9G,$I63K4*/EJB@WAF2KBN2,JU;L'$F#66\65%4[628]N<:FT7..%?]AP[= MT/!:T1DXG_$;O$F&L_KX7Q!D6?JUQW[[[Z
M@M2U<015[J[9W=YUY91G3/R8_6Q[.L\>*M7KFP3R*J=Z?U<\XD_+'/(.1".6 M9OB(;V[4]ENU/N[!U-T50&FG(_QFEN\6;YG6N&]$A4L&A(MH;F,^$:7R MY+]H+O>)&Z]Y=+J0)
M)W?O29)N[.^0/4YQ$9A1%MLHM-R=.Y$J,7O,WIW"Y+5.IW-RK8)* MV8_AV>/KFI9DL>S^/?I'0X^+ET%(UJI"V"9A)&52?6FMO'[PK%PJ9DGMK[0D MTFMP6&:*-5[BYC234!<#
[T.)-6N\3$W.P7FU35!1>FH#"R,5ZW19-6'R6_OE MTJ$T[EFS1W+/(6(>J&ADH=RXDD,OO0LW:@V;@W[V)+P-RS0XC0N_X0$P# @F MXB%&T@!F9F3?X]?I(7N#6I&-
EZ[!2L/(EF(B3AXV0BY8JOCEDXYZS1"~~

- ~~*#QLJDX!3@/$!0#\!WN \YQESC $DF!D).0Y#3-;!D+1RX*]ZBJ\Z\]86S MK*;IJOG: S&AC#"E*Q@LVMDHYMLDFA721%8SHA9P<4W5] M<[2]2?5A/"B4>W:+MI0%F[UZ]!0ZZ\N\<-
+&1!G+*RM^TG%N65]N&'4:AO+9 MV. C:+"PC67H5 Q;:*BZ5@D30[Y.#GG=?1=R+5B_9.H]55V@W>)NFBZ#QN@[M27($&F66G=ER_9!KU/'Y_*W!0[F3"D0IN&HF/+]NSJ87_-
B!G8U^RUBNQ60+ M.I2V JU8:'7(@6T0[3;-(2P&FE"(-%R,HHZZ@/$1D$S5,O&8,CGG,Q%[3PRR MF?*^V%M"PEHR3E?=$6J5J-I9H.[6R9I&.:W%(T1B\/+.F\M+R13-8D!=F!92
M9:&8R)>XBT0<$1'RZA583B7;Y:K*OD&L2V[2.E,HOH:%6RO!U"HT&9*C2I_Z M2Q&(WDFU>L$Y"$5G*'#G BA461GSYI*/&AUDBHNSO:.$B3;(1.'0P;3%[=#,61;-B>P(5]Q]
MH;0JE.031G>+[!7JH80F-*0R*@&$Q0$1 DY\OI/KO4#8?OEIRL;):FU_M"J M!<;,NU<7:H0./:GAR?F'V)ER1*,1;)1E\)4/XSA](@#M>.*>,(S?03A-3PY)
MN98G=RRR]5E6TB"&3J1B2O,WE J\G$R.6Y:*(MC">~~<>~~R=:H:TE(QI 2-'!/*0;67439/C H2_]K$<_A<[0UTVZCML&4+7?K(B?K6&,-1@9C! MA>\9'?%NGTP*:2&B?
5>GF,'@4H!M!K>I22L0*(>(4IXC/UJ.G]U:\&0F[VM, M\F)+PFWU,9S-.3K.W\>WW)X*C6;GAP+.0F;7?$)* M!MP:1[9T+E1HKZ6".R &NVG3 MQ]1S<12+6X*K3I@T8=
[0/#QF26[I]YH&]+3(C74%2WLS O),23D.8M-R>!FT MK5;(^T;M+,NW3"=RO^;-MTJGC,+@:4@XJ&R;5(5VI<:.M5I0KEC&/!1L1045 M*XCC2?@$C)(5))!,[$!@#_5X/;O97 T=J8?"
[)Q[F8TX;V=7%U:%2O2.&JBJ M2QWLRUK*GY"&M,L)$!X#QR5J&(J_S@1:!(.HT+8&IN,[&%K?M\[/"?'19>FP M#C)6-*_5\78FD<1PHQF1;NNRNGF9>H9$&ZUF/KL!%(PS> LTQ-
TP[B7:C.GD M*S(R9TE&=GCGZ?I[4[9; QS,2QFQ 'XC&T,8-X-:&-HT&8"C5),2#,'@V3(X7G XWLJ=W6+'>(I^+GL!7JY46\
MYUE&K"4F'CT9%'.,Y$0I[0O$W2DO(B="A13E[?)=DX$7CX& Q+=23?!%%4[\ M3_$/9&(9C,/3P&(P]"T\"VLU@]B6MP!WZC:=2D]CVFON^S!WF@BYD$QC2P= M>EO?
X@=.]F9@.M<$$=^G'-;M0NTO?Z7'VU. 2S-C)@EA*;ITE966/;78*#4; M/"056GHEW#'B:5B^%9246[=24>!F:Q$HQ5NW,Y3CT' D\+Y0[;[/#&;8Q+=D MU'LQM*HW!-K5#6J4:SWM2T
S#B22 MV73!<;"-KJ!]V",\O>-K@ZZ@@$DB>DA;58KK.\BC8HH=9QC1]C%881M@1+-P M^/WN2(S'K2M.K$_=V(M1CHB (DVEUFJQW"9UUEV@2ZKA5RW4*<0#PZU79F(Q
M%=]9V.K,-'=:YX8*LAI@/-V%H,D!H+B($S=;=QS/^$X$1)GCI&N6N4C(2KC7 M;CVA[]^)UZ9K.T-E66XY(.YL$*Z&V&A(."BOABL@PLM9;L:B_MZ\ MHU.P?-
;/Q"I(BR75#!_W*&1AVXT.]E3@.%)H#X&_<#WA,Q$$1!D@+,>T(&\6 MVSN3T@3?J+7/=WKC9.T7KT=8YB(JFTNP^0M)75?KY;3DR+E+%3D:V50D E)R M<4C$,;M-VT#Q40]="G#
(-738[U]8P"4IC8I_,[',J_9@*A#!N-K!W\LD2P MS(EQX1=8D53;>9$F) X#E?+6VHX+9_ TCEV6H97F;D\<(WL\]92J)XI>3;^H MIP*<_(IUA,KJ> K]2;3@"1Q+#W0*T),@[*R*5 I-<=
<845HP8JBGNMDUF@.W MMT;\$ -SN!!(!$F\',97G]_I/[6A35K!50IN0N=[QU@3+]]QA7?I;D2G8[ME
MDI=:^%2DZ$Q8XB%>/8MF>"A%VTU.)G=))F4A8=PA*RQ"FCHY=%ZY05(1:#4+ M,6Z.WY$V]9"FMMTK;7I,-[AHQ[8XB1CL6U^;2>Y.Q8QKDVG5;[)R$]1C6>NU M2/M,=5[/)N)8[:;
<)-G+U*%>+$*<8@'F)X]-9R/Q6W#O,6X]!$QTMHDPJ\(!HD^7&>_Y0;S=:AR=DWQYJQM ME9PGAR8@8_(T,]7Q)&R]BQU"3M(AYJK,4F\?-LEY-!PO,IR"SURLXEFYY2+= M
HW:*MR&1.D3+,Y7/2_7T."UXNF.][RLA*TH^-+R+O)$1BR/B7\9DRMKUZN/ M<4.8N8N$J^=Q\ZT) NK=WC U;E?Q[1^=99OY=\9!)-J21X^)TB,](B)T6PER MI6[5>3MDYC+;O$46?
F<6.,=1%[;!\;^$6QTU>3D6Y;.F+9Y&.F$FP!1]J[:*ID$6/"=- M. '*T\Q%IA2C%WG(&'Y#'D)7MB,\WD++Y?%T5/Q63L;3DA&0M8J-JN$>C=;:
ML^>2[6MH,ZF^CF4M89)PBYM4M"19EE).=0,H3GRUM_;G;AP"F8.@#R^ 'T#CD?QT21EZ]?4<0L;JVX7 =U"R+B.6>P4JF'EI>(6:2;0QF[I,PDG MUY]_=*YV+<'G^MC"E=;/;
<]-.V"/KK;X3EC&DD#1U(IN%$GLIY9X;X=$H@V, M5W)..ZW;&40!0P>*7DJLC#+NXKN@8=I4N " #US5BP..>/7EZ !Z_,=$60X9 MRYD7)4IJXJ+IDHBN M5-
M8JY%.E414!)TBBHU7*=!94AB6F9&7++CQCOA8=A/;KA/;D6]H8>J:-+9Y M'M#2Z6:,;2,L]CU)IA4ZU2&ZT8SDGCQ.)9I0-5AV_D8X$&@+$67!(#+B $L= M<[9\?KXJ.7&TS ,3.9-
O4_)7%RMDS)N-,PW!>UY-M#V":7/$5JAK;0'D.WE9 M0S"M0\#)P<$S;PD<+6'&%CF,&9M\.(5N)+:1PD1;E^RE?/&%:!N%Q^^QED5Y M9D*O)OX>0D$JC;)JG2;PT)((3#%JYE(%TT?
+18OF;9R]C553,7Y6Q4GJ*Z * M)&)-XD^%O&/FL-PO@? >WVVWDF.5UV-TR4!K5:6,[>9BS3CZ/:6:SSCF29QL M]*OG3&'"YY#M1:MB<+FTVR'#+NLHV
M^2Y^5E\FY)KT=$6*GH9[NL1*C348APT?04)2HNXM%(.IVB&)(#9(R(C&L7, MI*RATR2#B0?*$D?*X.MM1S]0MH,I80*J[QDD4 M(MVV?Q:S5PQ6:NVCR)D6#)_&NFRZ:[-
XR;N$3E.D Z);+T;GQN#/?*P+ FU7 M$&W68M4SC!:ZD5N,33(228V6_P!GM\4TBJU%C"L+!(/DH=M#5]DWBFZ M3+PDRMTN!+XBJIU2JP;-/9\;5<_6BWW7(E D%K7?:V>IW&6*&/)T
M"3%&3^CTU"HN5@-C&FL <'2%48F+^&G$S94Y-$6X4)#1=+, MDXBM9GI:ME*A7#'5E-&KE:2 0%VKTC6I@6#HQ%2MG@1\FX%JX%)4$5P34%-0 M"B42A]9_9]%B^ ,-,,"XSC,
<1]@F[9Y6- MH".AX5F#RQ6236:L8J+8L&+0Z#1NW*1 #')J?6GK._="O,_CF*FLI43)\K(. ME'./*S>(6!A%DVBD*WD+RYJH/K8(*MSN4;)&1%;>5V+D&[A'RL%;;6P,4Z4P
ML)2:_P!N!RU^.=M8XYEQE6LWXGR#B:T]_P" 9%]$_4G[I!NRE- M1B4DU=LB2\(NNE+0[ARU6*TDVC1T4AE$2AHA(Z7+/EFH:P7M'Q]@#+ M>9,P52Q7J0G,VPM#BK?
&V:RNYV((\H+ZZ.FK)O0.Z:'6;W12*28%7-PD/ M1L9!M(YD19 2:_/D>7&W37DL$RQLF@LR7[,%OO>4K?)U_*6&W>'HRB.86@.
M(#%\;*NH.1E;30I!W5EK'&V>:EX)M)S#I[+2#>7<,X D@@JWJ-5;PQ5;1Y6I MDKDK&5PQ_ WVQXRE+7 /(%M?*@A$+6RK
]3!!26KWQV/E(EM,MT15!D\0K3D>OWRX6F>N%'J5(DV\Z MQJ$5'"TJ-OQCCN8V-53<_=4;9?.1Q/#IWZZK7+;1L/A-M=\K=G@PH/D MXU)P]F(2MKR:KLM?B2LR7MY^I^OS6QV!,-
UK;YAW'F%J@XE'E36FID9[(%G&OGL-\MJ8QY9Z:>@<&"0-@ M67(I+W&;=JIN(^J)A<8BGR\'CO+M6R:_;6BJ1]B?.DJ@F_EHR-KD@\#QZR\< M6YK57\K(,S?\J5Z*EJR^2783C@@$B?
AG'KKHM@9*,:2T4^B'95E&,FR<,'1$ M'3EBN=L\1.@N"3UDJW>-%3)*& CEHN@Y0-PHW525*0Y2+SM.U?%>![W@QIC7Z(-VD*C#VVY5JYH.J](FEEG,4892 ;N9Q5VUD).5.PB
M&!9)"'8HL4"EOG]?WCCG)*E?/6U!UFW<%@K*4C]6_P!#<4QEV:SC62JLN&59 M-S;(*8KZ)*IDVL4_JL RCIN3-(P#9J9"??O$7LFLJ:%B"H$B)UR/*T?YAR MUUU4Q8+Q
[PSMQQG@\DC'3[S'&+JWCU.3.R<,HJ56KE<:0B;HS 73ATV8.A: ME.9KYQ5=) PHEE5KLSRBV=H5F/<722C:9&+.LBQ#KR$;%')&-,?1S%HHY<6RTRRY
M5;7;P=H\KN=DH.78ZMYKR)FF3L%OQ6:.S&^F[]3J[6W"$ M=>X>RD;P[0\I&R]FL,5'QS.$LDG(1R+Z/&)AF\6J4&0$1:PX 1^RVLWE[3K3
MNHC\0QL/EZ3QO%XSRS2LH2\"W@49B*O#FGVJN3C%"361E(>68.8V/C)MK"J, MY 624G.IRSQ@X>0T0NU)W<8TS/B.)UY38??85M/?;-,&J8??7%M=#C<9RS(/
M(R#/6X*):23:,CFD) PRLL,.&C-%M#I23]5U(.GDE8I2;EWKIV\D%W2Q5;K: M(FB+1FX8DS_)[XL;Y8A;$_2P+!8\0B;'"$R79X^)&4089G;344ZQ(@3Z(V23
MLTY<,.6*.O4@8TS7&F+92(:K-6\P+>7*<+)O#& <88ZM,Y8K';H*LME+C,6B[6W(DFYMTLJM-69%"W7 MF:L-IE(1A-R+Z/K82TR_<,Z\UC&(KG*W
=%!&8UOXK2+>'MWWNWN5W!NMM.7 MG-59Y'H^"6M9:3M\L,(2"F:+*9I O%LA"V]W;U;*-TV\7NLXG@G5BR3*Q<6V@8N+RE
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;=IFH1S56P9(=XV3A%$8?(UEQP MM)6@85LU?GBLG0[-:U5E9=X1TI'V)JW;2A%C(**.HM155\T(1,96X^OI\CI5 MLDV\;O,4YEF[?G^X2=IK4G@?%%--
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ETVSB,FH22 M:U%C9*?&RD&ZOSV7.5XYY_(9-&YSC,+0-8;6O)$L M>_.&.1F=,9Q)['=)N/3;#='S>>(I*S4DV013L+PJ[@&Y4W0I@3QS)%QW"T6B M/GST!V3;9-]V*?++Z>:]BM%4T1-
$3 M1$T1-31T1-31T1-31T1-$7G]N0V0R>X++L9D,F624FODA,/LYN 841 MM+VIQ-8*RC:LN8_F:O>'MC19U5,]ILP-[4S7IU@:C\%0RDNQN$78X.*F(5G&4Q-
*>*7GE/E'U]0INR-V?62W*M(OH/)TU<&3EPDO;*XG"R,74*6K*1ZA$9=TK%V=1U$K/Z MTS81@N$+"U)?EGY?73SY*+K%V1\G:HIU#3&XY\M$R52F822@5J#)2=7"1?
8UE7Z:R:B+.)LTS/SW"/YRYS[5M#RI!M83 MOKM!VG36UU+)9)C+MERRKD2UC9RNK(642.-.Q MT;6#.X"(K<4ZBC_!$7*Q5;HZ(FB)HB:(FB+SVWP[1[KN>EL>.*DXQ^P"N4;*
M],+9+@[GV]CQC8$(>;W.33NNVJQ9EG+%+5.VRC>%J5:?4>C&Q MA"5]:V-Y2S0UD3R]7WLZ#-"O6^H1&.[3=ZJ[7=@UJ[23)?IESUN./?SE9[8=
MON^M>I;7Z'&9N3C;-34\H.LO9+B;K=GL.=1:YU"3QHK(M[&9S9,K2L544YZ- M=1=E;Q]7L4DE)%DJO2<>P;$RGP '3+O\ #,9DX%-;).T"L5:^C4OO%(]0F
M*_D.J619S:LA%9"G;\51%+6NTK/K42C87"R'K]*CK M*WA(EVF56;7G9SO:FJ\FUIV[F1J3V,Q=BBH5J$B[%:HJ-B)2N6-Z\R W>69& M*D9.P.I:N_!HJ(RE.0#^XR!X]VE-
P3=M)N>2*SR6R/>5-W6JW.LDRBN+*\,X>=2FO%D[,XD0=E+ M3&N?KP'DMA-BF#=X6,3O;+NDSE(Y*/8<9XPC4*D[GC3 5:XQ-3@VEP%R@,&1 M@F^;3C271-
8H"RO4+J$DM,SD#L[>2CXJZEL].,R$)QW M7GR[4MB8"\09*$$'!"G;J%#PX\I_;Q7GVUG>UNQ]'U:LRZ-2L9W3/"F-6UE+ M&QEY,YM%@JH5'(63Y=W78F/?Q-?
I=AE290GW=T9Q\7/%HLG7(N28*7&"C%"D M@C/7F#,G3/,&!RMDILG;5VB,#AVY$>PI)/)[K<74Z[09*IQ-"EWS_"4Y,PZ$ MY/'K?
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O'C$])M<:<9U71FZ_P!I_^UV!(_$^%_P-[9JO8MXVDW ME9-D&5PC+Q4+.>??,)AO,OT9)Y'1S,SB3\RJ0DY&R$\V? M.K&Y_3C&7G'#1($WF/-9!LYR!VC.1,BUZ>S57TJ_@([F_,50N5
M%BJ+D^0;Q4I?(R =6:J+.XB:K\F[4:8_>P3V'B'<%)PIK@I)Q:)Y&LRT>3Z] M>,].$]UK+UHT531$T1-$31%\')E"-US)<^*5%0R?=*!Q\0"&$@ 0>.^(&X^S MZF]
ZCHB\+\3;L>T2K=0GIXVRX9#N6RVVO M>5N,SG:\,O;#MSDZ1BG,%%LEL3LC=A9)A:FNHF1N#**1N%F.R9TE@QL;>K1< MC64(UY,3L^SO$&NI'0;-@]_E'IQ%Y'/A_;BGE?
UY$^HX%15C'?IO.R+4\<6 MQEL^<.(J\?#7Z4N@QR7&13IG,L2+*Q)!>U-\]K98)M>K]8E\A3S1Q2;0RQ. M[K%1^*V6VQ?D2F=IRN8X^?.T'X3?Z9NVWURT/DFWRVU2?5/";>F=LI-
!^AMF MJ#B9R['VK.C&P,OB5H?C,/84\/5<1!'U,D,SO\LG= FXB$5:^=;1Y7O^' #Q MF_"\1DKRGNXWOLK3.5F>VE@DPA+] 5(USA8O)TW$244M6[=(N;'$QD76)%63
MA;7.U^NP<3.,9=5AC<]X;KY+023KKT9$EC?D;C3OTL9U44CN^[1"N4&HUZ6V MLV:S9 FD'#64NL+1+:9O'-Y>9Q'S3^,;0ZD)"SU>LEQF5Y2.>(KP9GCYW M.&J2KIF"QT
M6QU0:KG.@"IV[B)P'R#\ MM$5=$31$T1-$5.Z41Y$ $?GP'/YZ(JZ(FB)HB:(FB)HB:(FB)HB:(FB)HBH(M /J #^(/R_\@_(-$5!(0>.2E'CCCDH#QQZ<B)P'R#W]@]_7_?Y^^B(!2AZ% /P
_LT1. 'U !_5HB=TO\ LA^0?/G^ MWK^/71%Q,4HAP)2B')0X$ $..\'3CCTT1<@*4.. ./3@ #CGGGC\>1_,=$5 M=$31$T1-$31$T1<1*40X$I1#IT$
$.GIT$/;V^6BD#@/4_4^)7'PR%*8"D(4 M![PB!2@ "(^HB !QR/N/OHI_*>6]'*"8CA&BJ4A. ^R7T#_1#Y?AHLE4"$*' M!2% /D!0 /R .-$3N$_V2^O/]$/7GO<^GKWNOX]?
71%7@/D'Y!HB=TO^R7IZ M= Z:(OCX9/&[W<)WA*(";NAR(=TH<"/'(AQTX'VZ>FB+[Z(FB)HB:(FB)HB: #(O_9 end~~

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Disclosure - Property and Equipment, Net link:presentationLink link:calculationLink link:definitionLink 995525 - Disclosure - Accrued Expenses and Other Current Liabilities link:presentationLink link:calculationLink link:definitionLink 995535 - Disclosure - License Agreement and Clinical Research Organization link:presentationLink link:calculationLink link:definitionLink 995545 - Disclosure - Notes Payable link:presentationLink link:calculationLink link:definitionLink 995555 - Disclosure - Convertible Debentures link:presentationLink link:calculationLink link:definitionLink 995565 - Disclosure - Redeemable Convertible Preferred Shares link:presentationLink link:calculationLink link:definitionLink 995575 - Disclosure - Common Shares link:presentationLink link:calculationLink link:definitionLink 995585 - Disclosure - Share-Based Compensation link:presentationLink link:calculationLink link:definitionLink 995595 - Disclosure - Net Loss Per Share link:presentationLink link:calculationLink link:definitionLink 995605 - Disclosure - Income Taxes link:presentationLink link:calculationLink link:definitionLink 995615 - Disclosure - Leases link:presentationLink link:calculationLink link:definitionLink 995625 - Disclosure - Commitments and Contingencies link:presentationLink link:calculationLink link:definitionLink 995635 - Disclosure - Related Party Transactions link:presentationLink link:calculationLink link:definitionLink 995645 - Disclosure - Subsequent Events link:presentationLink link:calculationLink link:definitionLink 995655 - Disclosure - Summary of Significant Accounting Policies (Policies) link:presentationLink link:calculationLink link:definitionLink 995665 - Disclosure - Summary of Significant Accounting Policies (Tables) link:presentationLink link:calculationLink link:definitionLink 995675 - Disclosure - Reverse Recapitalization (Tables) link:presentationLink link:calculationLink link:definitionLink 995685 - Disclosure - Fair Value Measurements (Tables) link:presentationLink link:calculationLink link:definitionLink 995695 - Disclosure - Marketable securities (Tables) link:presentationLink link:calculationLink link:definitionLink 995705 - Disclosure - Property and Equipment, Net (Tables) link:presentationLink link:calculationLink link:definitionLink 995715 - Disclosure - Accrued Expenses and Other Current Liabilities (Tables) link:presentationLink link:calculationLink link:definitionLink 995725 - Disclosure - Notes Payable (Tables) link:presentationLink link:calculationLink link:definitionLink 995735 - Disclosure - Convertible Debentures (Tables) link:presentationLink link:calculationLink link:definitionLink 995745 - Disclosure - Common Shares (Tables) link:presentationLink link:calculationLink link:definitionLink 995755 - Disclosure - Share-Based Compensation (Tables) link:presentationLink link:calculationLink link:definitionLink 995765 - Disclosure - Net Loss Per Share (Tables) link:presentationLink link:calculationLink link:definitionLink 995775 - Disclosure - Income Taxes (Tables) link:presentationLink link:calculationLink link:definitionLink 995785 - Disclosure - Leases (Tables) link:presentationLink link:calculationLink link:definitionLink 995795 - Disclosure - Description of Business - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 995805 - Disclosure - Summary of Significant Accounting Policies - Additional Information (Detail) link:presentationLink link:calculationLink link:definitionLink 995815 - Disclosure - Summary of Significant Accounting Policies - Summary of Estimated Useful Life of Each Asset (Details) link:presentationLink link:calculationLink link:definitionLink 995825 - Disclosure - Reverse Recapitalization -Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 995835 - Disclosure - Reverse Recapitalization - Summary of Net Proceeds from Reverse Recapitalization and PIPE Financing (Details) link:presentationLink link:calculationLink link:definitionLink 995845 - Disclosure - Reverse Recapitalization - Summary of Number of Common Shares Outstanding (Details) link:presentationLink link:calculationLink link:definitionLink 995855 - 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Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 995875 - Disclosure - Fair Value Measurements - Schedule of Fair Value Hierarchy for Financial Assets Measured at Fair Value (Details) link:presentationLink link:calculationLink link:definitionLink 995885 - Disclosure - Fair Value Measurements - Schedule of Convertible Debentures Embedded Derivative Liabilities (Details) link:presentationLink link:calculationLink link:definitionLink 995895 - Disclosure - Fair Value Measurements - Summary of Change in Estimated Fair Value of Convertible Debentures Embedded Derivative Liabilities (Details) link:presentationLink link:calculationLink link:definitionLink 995905 - Disclosure - Fair Value Measurements - Summary of Change in Estimated Fair Value of Debt Instrument (Details) link:presentationLink link:calculationLink link:definitionLink 995915 - Disclosure - Fair Value Measurements - Assumptions Used to Determine Fair Value of Preferred Share Warrant Liabilities (Details) link:presentationLink link:calculationLink link:definitionLink 995925 - Disclosure - Fair Value Measurements - Summary of Change in Estimated Fair Value of Warrant Liabilities (Details) link:presentationLink link:calculationLink link:definitionLink 995935 - Disclosure - Marketable securities - Schedule of Marketable Securities (Details) link:presentationLink link:calculationLink link:definitionLink 995945 - Disclosure - Marketable securities - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 995955 - Disclosure - Property and Equipment, Net - Summary of Property and Equipment (Details) link:presentationLink link:calculationLink link:definitionLink 995965 - Disclosure - Property and Equipment, Net - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 995975 - Disclosure - Accrued Expenses and Other Current Liabilities - Summary of Accrued Expenses and Other Current Liabilities (Details) link:presentationLink link:calculationLink link:definitionLink 995985 - Disclosure - License Agreement and Clinical Research Organization - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 995995 - Disclosure - Notes Payable - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 996005 - Disclosure - Notes Payable - Schedule of Carrying Value of Term Loan (Details) link:presentationLink link:calculationLink link:definitionLink 996015 - Disclosure - Notes Payable - Schedule of Estimated Future Principal Payments Due Under the Loan Agreement (Details) link:presentationLink link:calculationLink link:definitionLink 996025 - Disclosure - Convertible Debentures - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 996035 - Disclosure - Redeemable Convertible Preferred Shares - Additional Information (Details) link:presentationLink 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link:calculationLink link:definitionLink 996105 - Disclosure - Share-Based Compensation - Summary of Stock Option Activity (Parenthetical) (Details) link:presentationLink link:calculationLink link:definitionLink 996115 - Disclosure - Share-Based Compensation - Summary of Share-based Compensation Expense (Details) link:presentationLink link:calculationLink link:definitionLink 996125 - Disclosure - Net Loss Per Share - Summary of Basic and Diluted Net Loss Per Share (Details) link:presentationLink link:calculationLink link:definitionLink 996135 - Disclosure - Net Loss Per Share - Summary of Diluted Net Loss Per Share Attributable To Common Shareholders (Details) link:presentationLink link:calculationLink link:definitionLink 996145 - Disclosure - Income Taxes - Summary of Loss Before Provision for Income Taxes (Details) link:presentationLink link:calculationLink link:definitionLink 996155 - Disclosure - Income Taxes - Summary Of Components Of The Provision For (Recovery Of) Income Taxes (Details) link:presentationLink link:calculationLink link:definitionLink 996165 - Disclosure - Income Taxes - Summary of Reconciliation of Company's Statutory Income Tax Rate (Details) link:presentationLink link:calculationLink link:definitionLink 996175 - Disclosure - Income Taxes - Summary of Net Deferred Income Tax (Details) link:presentationLink link:calculationLink link:definitionLink 996185 - Disclosure - Income Taxes - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 996195 - Disclosure - Leases - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 996205 - Disclosure - Leases - Schedule of Components of Operating Lease Cost (Details) link:presentationLink link:calculationLink link:definitionLink 996215 - Disclosure - Leases - Summary of Cash Paid for Amounts Included in the Measurement of the Operating Lease Liabilities (Details) link:presentationLink link:calculationLink link:definitionLink 996225 - Disclosure - Leases - Schedule of Maturities of Operating Lease Liabilities (Details) link:presentationLink link:calculationLink link:definitionLink 996235 - Disclosure - Related Party Transactions - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink 996245 - Disclosure - Subsequent Events - Additional Information (Details) link:presentationLink link:calculationLink link:definitionLink Description of Business [Table]Description of business.Statement [Line Items]Old enGene's Equity and Convertible Note HoldersOld enGene's Equity and Convertible Note Holders [Member]Old enGene’s equity and convertible note holders.Note payable currentNotes Payable, CurrentNotes Payable, Current, TotalCurrent portion of note payableDebt instrument, interest rateInterest rateDebt Instrument, Interest Rate During PeriodDebt Instrument [Axis]Cybersecurity Risk Board of Directors Oversight [Text Block]Transaction costs as part of reverse recapitalization and pipe financingTransaction Costs Of Reverse Recapitalization And PIPE FinancingTransaction costs of reverse recapitalization and pipe financing.Additional awards approved for issuanceAdditional Awards Approved For IssuanceAdditional awards approved for issuance.Deferred tax assets, note payableDeferred Tax Assets, Note PayableNote payableLong term marketable securitiesLong Term Marketable Securities [Member]Long Term Marketable SecuritiesInterest expense, including the amortization of debt discountsInterest Expense Including Amortization Of Debt DiscountsInterest expense including amortization of debt discounts.Plan Name [Domain]One-time payment for milestone productMilestone Product PaymentMilestone product paymentRestricted investmentsRestricted InvestmentsInitial annual base rentInitial Annual Base Rent Per Square FootInitial annual base rent per square foot.Company ShareholdersCompany Shareholders [Member]Company shareholders member.Entity Address, Postal Zip CodeCybersecurity Risk Board Committee or Subcommittee Responsible for Oversight [Text Block]Deferred tax assets, operating lease liability.Deferred Tax Assets, Operating Lease LiabilityOperating lease liabilityFair Value, Recurring and Nonrecurring [Table]Entity Incorporation, State or Country CodeCash paid for interestInterest Paid, Excluding Capitalized Interest, Operating ActivitiesVesting Immediately Upon Grant DateTranche OneShare-Based Payment Arrangement, Tranche One [Member]Tax creditsEffective Income Tax Rate Reconciliation, Tax Credit, PercentEffective Income Tax Rate Reconciliation, Tax Credit, Percent, TotalOther Comprehensive Income (Loss), Tax [Abstract]Other comprehensive loss:Business combination reverse recapitalization descriptionBusiness Acquisition, Description of Acquired EntityBeginning balance (in shares)Ending balance (in shares)Shares, OutstandingFair Value Hierarchy and NAV [Axis]Business combination event shares issued on exchange of common share warrants.Business combination event shares issued on exchange of common share warrantsBusiness Combination Event Shares Issued On Exchange Of Common Share Warrants1May 2023 NotesMay Two Thousand Twenty Three Notes [Member]May two thousand twenty three notes.Auditor NameLevel 2Fair Value, Inputs, Level 2 [Member]Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]Long-Term Debt, Type [Domain]Applied to Refinance of Amount OutstandingApplied to Refinance of Amount Outstanding [Member]Applied to refinance of amount outstanding.Convertible Bridge Financing [Member]Convertible Bridge Financing [Member]Convertible bridge financing.Reverse recapitalization embedded derivative fair value of embedded derivativeReverse Recapitalization Embedded Derivative Fair Value Of Embedded DerivativeReverse recapitalization embedded derivative fair value of embedded derivative.Fair Value, Measurement with Unobservable Inputs Reconciliation, Recurring Basis, Asset Transfers Into Level 3Assets transfers or reclassifications into level 3Redeemable Convertible Preferred SharesPreferred Stock [Text Block]LeasesLessee, Operating Leases [Text Block]Commitments and ContingenciesCommitments and Contingencies Disclosure [Text Block]Debt securities unrealized losses.Debt Securities Unrealized LossesDebt securities unrealized lossesStock, Class of Stock [Table]Latest Tax Year2043Area of office spaceRentable square feetArea Of SpaceArea of space.Class B-1 Redeemable Convertible Preferred SharesClass B-1 Redeemable Convertible Preferred Shares [Member]Class b-1 redeemable convertible preferred shares.Ending balanceBeginning balanceConvertible Notes Payable, CurrentGovernment Assistance Programs for Research and Development ExpendituresGovernment Assistance Programs For Research And Development Expenditures [Policy Text Block]Government assistance programs for research and development expenditures.Lender Name [Axis]Depreciation and amortization expenseDepreciation, Depletion and AmortizationDepreciation, Depletion and Amortization, TotalPercentage of prepayment premium of principal amount outstanding of the closing datePercentage of Prepayment Premium of Principal Amount Outstanding of the Closing DatePercentage of prepayment premium of principal amount outstanding of the closing date.Percentage of vesting rightsShare-Based Compensation Arrangement by Share-Based Payment Award, Award Vesting Rights, PercentageCollaborative Arrangement and Arrangement Other than Collaborative [Domain]Payment Of Issuance Costs Associated With Convertible DebenturesPayment of issuance costs associated with convertible debentures.Payment of issuance costs associated with April 2023 NotesSupplemental disclosure of non-cash investing and financing activitiesNoncash Investing and Financing Items [Abstract]Entity Listings [Line Items]Class of Treasury Stock [Table]Domestic (Canada)Deferred Federal, State and Local, Tax Expense (Benefit)Deferred Federal, State and Local, Tax Expense (Benefit), TotalRelated Party Transaction [Line Items]Cybersecurity Risk Management Processes Integrated [Text Block]Interest expenseInterest Expense, NonoperatingInterest Expense, Nonoperating, TotalCommon SharesEquity [Text Block]Title and Position [Axis]Class of Warrant or Right [Axis]Old enGene Shareholders (Excluding Convertible Notes)Old EnGene Shareholders [Member]Old EnGene shareholders.Sale of Stock [Domain]Note payable, including End of Term ChargeLong-Term Debt, GrossApril 2023 NotesApril Two Zero Two Three Notes [Member]April two zero two three notes.Fair Value Measurement Inputs and Valuation Techniques [Line Items]CIKEntity Central Index KeyReverse Recapitalization And Pipe Financing Transaction Costs Included Within Accrued Expenses And Accounts PayableReverse recapitalization and pipe financing transaction costs included within accrued expenses and accounts payable.Reverse Recapitalization and PIPE financing transaction costs included within accrued expensesCash equivalentsCash Equivalents, at Carrying ValueCash Equivalents, at Carrying Value, TotalWarrants, each exercisable for one Common share, at an exercise price of $11.50 per shareWarrant LiabilitiesWarrants to purchase common sharesAuditor Opinion [Text Block]Auditor OpinionIncrease (Decrease) in Operating Capital [Abstract]Changes in operating assets and liabilities:Fair Value, Liabilities Measured on Recurring Basis, Unobservable Input Reconciliation [Table]Issuance of common shares upon exercise of warrantsStock issued during period value warrants exercised.Stock Issued During Period Value Warrants ExercisedInvestment tax credit receivableInvestment tax credit receivableIncrease (Decrease) In Investment Tax Credit ReceivableIncrease (decrease) in investment tax credit receivable.Proceeds from issuance of term loanProceeds from Issuance of DebtCommon Stock, Shares, IssuedCommon stock shares issuedCommon shares issued and soldProceeds from Convertible DebtProceeds from convertible debtProceeds from issuance of April 2023 NotesRisk-free interest rate, MinimumShare-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Risk Free Interest Rate, MinimumConvertible debenture embedded derivative liabilitiesDeferred Tax Assets Convertible Debenture Embedded Derivative LiabilitiesDeferred tax assets convertible debenture embedded derivative liabilitiesFair Value Measurement Inputs and Valuation Techniques [Table]Common stock outstanding after reverse recapitalization and pipe financing.Common Stock Outstanding After Reverse Recapitalization and PIPE FinancingTotal Common Shares outstanding immediately after the Reverse Recapitalization and PIPE FinancingMeasurement Input, Expected Dividend YieldMeasurement Input, Expected Dividend Rate [Member]Prepaid expenses and other assetsIncrease (Decrease) in Prepaid Expense and Other AssetsFEAC Shareholders, including sponsor's and shareholder with non-redemption agreementFEAC Shareholders [Member]FEAC shareholders.Advance subject to achievement of specified interim milestone.Advance Subject to Achievement of Specified Interim Milestone [Member]Advance Subject to Achievement of Specified Interim MilestoneDescription of BusinessBusiness Description and Basis of Presentation [Text Block]Long-Term Debt, Maturity, Year Four2028Income Statement [Abstract]Entity Address, State or ProvinceClass A Redeemable Convertible Preferred SharesClass A Redeemable Convertible Preferred Shares [Member]Class a redeemable convertible preferred shares.Fair value of debt instrumentDebt Instrument, Fair Value DisclosureDebt Instrument, Fair Value Disclosure, TotalWarrants to purchase common sharesWarrant To Purchase Common Stock [Member]Warrant To Purchase Common Stock.Class B Redeemable Convertible Preferred SharesClass B Redeemable Convertible Preferred Shares [Member]Class b redeemable convertible preferred shares.Payment of target annual bonus netoff taxes and withholdings.Payment Of Target Annual Bonus Netoff Taxes And WithholdingsPayment Of Target Annual Bonus Netoff Taxes And WithholdingsNet loss before provision for income taxesIncome (Loss) from Continuing Operations before Income Taxes, Noncontrolling InterestLoss before income taxesNet loss before income taxesNote payable, net of current portionNotes Payable, NoncurrentNotes Payable, Noncurrent, TotalLicense Agreement [Table]License Agreement TableOff-balance sheet concentrations of credit riskConcentration risk credit risk off balance sheet risk.Concentration Risk Credit Risk Off Balance Sheet RiskRepayments of Other Long-Term DebtRepayment of other long term debtNumber of common stock warrants exercised by investors on cashless basisNumber of common stock warrants exercised by investors on cashless basis.Number Of Common Stock Warrants Exercised By Investors On Cashless BasisPIPE FinancingPIPE financing.PIPE Financing [Member]Aggregate sale of convertible promissory notes, warrants, preferred shares, common shares, or combined thereofAggregate Sale Of Convertible Promissory Notes Warrants Preferred Shares Common Shares Or Combined ThereofAggregate sale of convertible promissory notes warrants preferred shares common shares or combined thereof.Equity, Class of Treasury Stock [Line Items]Stock issued during period shares cashless exercise of warrants.Stock Issued During Period Shares Cashless Exercise Of WarrantsIssuance of common shares upon cashless exercise of warrants (in shares)Accrued financing costsAccrued financing costs.Accrued Financing CostsDescription of Business [Line Items]Description of business.Debt Securities, Available-for-Sale, Unrealized Loss Position, TotalDebt Securities, Available-for-Sale, Unrealized Loss PositionCredit lossesFair Value OptionFair Value Option [Policy Text Block]Fair value option.Embedded derivative liability measurement term.Embedded Derivative Liability Measurement TermEmbedded derivative liability measurement termLine of credit, maturity dateLine of Credit Facility, Expiration DateLease Cost:Lease, Cost [Abstract]2022 Notes and BDC NotesConvertible Debentures Embedded Derivative Liabilities for 2022 Notes and BDC Notes [Member]Convertible debentures embedded derivative liabilities for 2022 notes and BDC notesPayments of debt issuance costs associated with the term loanPayments of Debt Issuance CostsJune 2023 FinancingJune Twenty Twenty Three Financing [Member]June Twenty Twenty Three Financing Member.Fair Value, Measurement with Unobservable Inputs Reconciliation, Liability, Transfers Into Level 3Liabilities transfers or reclassifications into level 3Foreign exchange rate translation adjustmentFair Value Net Derivative Asset Liability Measured On Recurring Basis Unobservable Inputs Reconciliation Foreign Exchange Rate

Translation AdjustmentFair value net derivative asset liability measured on recurring basis unobservable inputs reconciliation foreign exchange rate translation adjustment.CoverCover [Abstract]Subsequent Event [Line Items]Comprehensive LossComprehensive Income, Policy [Policy Text Block]Earnings Per Share, Basic, TotalEarnings Per Share, BasicNet loss per share of common shares, basicIncome Tax Contingency [Line Items]Unrealized Holdings GainsDebt Securities, Available-for-Sale, Accumulated Gross Unrealized Gain, before TaxIncome Tax Contingency [Table]Exercise price equal to percentage of aggregate amount of term loansPercentage of Aggregate Term Loan FundedPercentage of aggregate term loan funded.Operating Expenses [Abstract]Operating expenses:Convertible notes netConvertible Notes PayableConvertible Notes Payable, TotalPrior Loan AgreementPrior Loan Agreement [Member]Prior loan agreement.Document Annual ReportTranche TwoTranche Two [Member]Tranche two.Debt Securities, Available-for-Sale, Continuous Unrealized Loss Position, Less than 12 Months, Number of PositionsNumber of unrealized loss positionRemaining shares reserved for future issuance under the 2023 PlanShares Reserved For Future Issuance Under The 2023 Plan [Member]Shares Reserved For Future Issuance Under The 2023 Plan.Investments, Debt and Equity Securities [Abstract]Total share-based compensation expenseStock-based compensation expenseShare-Based Payment Arrangement, ExpenseNote payable, net of discountLong-Term DebtPercentage of shares owned by shareholdersPercentage Of Shares Owned By ShareholdersPercentage of shares owned by shareholders.Deferred Tax Assets, Net [Abstract]Deferred tax assets:Accumulated deficitRetained Earnings (Accumulated Deficit), TotalRetained Earnings (Accumulated Deficit)Accumulated deficitCashless warrant exercises.Cashless Warrant Exercises [Member]Cashless Warrant ExercisesPlan Name [Axis]Settlement of derivative liability upon repayment and conversion of convertible debenturesSettlement Of Derivative Liability Upon Repayment And Conversion Of Convertible DebenturesSettlement of derivative liability upon repayment and conversion of convertible debentures.Cash Warrant ExercisesCash warrant exercises.Cash Warrant Exercises [Member]Stock issued during period value cashless exercise of warrants.Stock Issued During Period Value Cashless Exercise Of WarrantsIssuance of common shares upon cashless exercise of warrantsNumber of shares outstanding, Ending balanceNumber of shares outstanding, Beginning balanceShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, NumberAssets, Current [Abstract]Current assets:Common stock shares reserved for future issuanceCommon Stock, Capital Shares Reserved for Future IssuanceAggregate number of common shares reserved for future issuanceNet deferred tax assets (liability)Deferred Tax Liabilities, NetCash flows from operating activitiesCash flows from operating activitiesNet Cash Provided by (Used in) Operating ActivitiesNet cash used in operating activitiesAggregate Intrinsic Value, Options unvestedShare Based Compensation Arrangement By Share Based Payment Award Options Unvested Aggregate Intrinsic ValueShare based compensation arrangement by share based payment award options unvested aggregate intrinsic value.Entity Address, CountryNotes purchase principal amountDebt Instrument, Issued, PrincipalOptions vested and exercisableShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and Expected to Vest, Exercisable, NumberAccumulated other comprehensive lossAccumulated Other Comprehensive Income (Loss), Net of TaxAccumulated Other Comprehensive Income (Loss), Net of Tax, TotalOperating lease initial termLessee, Operating Lease, Term of ContractDebt Instrument [Line Items]Tax Period [Domain]Amended 2022 Financing [Member]Amended 2022 Financing [Member]Amended 2022 financing.Net operating loss carryforwardsOperating Loss CarryforwardsProperty and equipment, netProperty and equipment, netProperty, Plant and Equipment, NetLessee, Operating Lease, Liability, to be Paid, Year Four2028Net Cash Provided by (Used in) Operating Activities [Abstract]Cash Flows from operating activities:Fair Value Measurement RecurringFair Value, Recurring [Member]Maximum hours of CEO devote per week to providing transition services.Maximum Hours Of CEO Devote Per Week To Providing Transition ServicesMaximum hours of ceo devote per week to providing transition servicesCurrent expense (benefit):Current Income Tax Expense (Benefit), Continuing Operations [Abstract]Vesting [Axis]Total Convertible debenturesConvertible debtConvertible DebtConvertible Debt, TotalCommon Stock, Par or Stated Value Per ShareCommon shares price per shareOptions to purchase common sharesCybersecurity Risk Management Positions or Committees Responsible [Text Block]Fair value of common shares and exercise price of optionsShare Based Compensation Arrangement By Share Based Payment Award Fair Value of Common Shares and Exercise Price of OptionsShare based compensation arrangement by share based payment award fair value of common shares and exercise price of options.Redeemable convertible preferred shares valueTemporary Equity, Carrying Amount, Attributable to ParentEnding balanceBeginning balanceMeasurement Input Type [Domain]Reverse RecapitalizationReverse Recapitalization TextBlockReverse Recapitalization TextBlockStatement of Cash Flows [Abstract]Counterparty Name [Axis]Class C WarrantsClass C Warrants [Member]Class C Warrants.Antidilutive Securities, Name [Domain]First Amendment to Amended and Restated Loan and Security Agreement [Member]First amendment to amended and restated loan and security agreement.First AmendmentChange in fair value of warrant liabilitiesFair Value, Measurement with Unobservable Inputs Reconciliation, Recurring Basis, Liability, Period Increase (Decrease)Fair Value, Measurement with Unobservable Inputs Reconciliation, Recurring Basis, Liability, Period Increase (Decrease), TotalWarrant issued to purchase preferred sharesShare warrants issuedNumber of securities into which the class of warrant or right may be convertedAll EntitiesEntity [Domain]OtherDeferred Tax Assets, OtherWeighted-Average Exercise Price, Options unvestedShare Based Compensation Arrangement By Share Based Payment Award Options Unvested Weighted Average Exercise PriceShare based compensation arrangement by share based payment award options unvested weighted average exercise price.Amended Loan AgreementAmended Loan Agreement [Member]Amended loan agreement.Reverse Recapitalization [Line Items]Reverse recapitalization.Equity Components [Axis]Entity Address, Address Line OneMay 2023 NotesMay Twenty Twenty Three Notes [Member]May Twenty Twenty Three Notes.Settlement upon the consummation of the Reverse RecapitalizationSettlement upon the consummation of the Reverse RecapitalizationSettlement and extinguishmentExtinguishment of Debt, AmountSummary of Basic and Diluted Net Loss Per ShareSchedule of Earnings Per Share, Basic and Diluted [Table Text Block]Employee compensation and related benefitsEmployee-related Liabilities, CurrentEmployee-related Liabilities, Current, TotalRelated Party Transaction [Table]Cybersecurity Risk Process for Informing Board Committee or Subcommittee Responsible for Oversight [Text Block]Computer EquipmentComputer Equipment [Member]Property, Plant and Equipment [Line Items]Cash - FEAC's Trust Account and Cash (net of redemptions and cash paid for FEAC expenses prior to close)Proceeds from trust account.Proceeds From Trust AccountProceeds from trust accountSubsequent Event Type [Axis]Deferred expense (benefit)Deferred Income Tax Expense (Benefit), Continuing Operations [Abstract]Total other (income) expense, netTotal other (income) expense, netNonoperating Income (Expense)Summary of Shares Excluded from Computation of Diluted Net Loss Per ShareSchedule of Antidilutive Securities Excluded from Computation of Earnings Per Share [Table Text Block]Line of credit, maximum amount availableTerm loan facility aggregate principal amountLine of Credit Facility, Maximum Borrowing CapacityRisk-free interest rateShare-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Risk Free Interest RateUS Treasury and Government [Member]Preferred share warrants fair valuePreferred Share Warrants Fair ValuePreferred share warrants fair value.Change in fair value of convertible debenture embedded derivative liabilitiesFair Value, Net Derivative Asset (Liability) Measured on Recurring Basis, Unobservable Inputs Reconciliation, Gain (Loss) Included in EarningsAnnual maintenance feeCost, MaintenanceMay 2023 NotesMay Two Zero Two Three Notes [Member]May two zero two three notes.Investments in Debt and Marketable Equity Securities (and Certain Trading Assets) Disclosure [Text Block]Marketable securities2023 WarrantsTwo Thousand Twenty Three Warrants [Member]Two thousand twenty three warrants.Entity Voluntary FilersInterest rateRelated Party Transaction, RateBusiness combination aggregate commitment amountBusiness Combination Aggregate Commitment AmountBusiness combination aggregate commitment amount.End of term chargeEnd of Term ChargeEnd of term charge.AmendmentAmendment FlagTotal current expense (benefit)Total current expense (benefit)Current Income Tax Expense (Benefit)Initial consulting period.Initial Consulting PeriodInitial consulting PeriodDeferred tax liabilities, operating lease-right of use asset.Deferred Tax Liabilities, Operating Lease-right Of Use AssetOperating lease-right of use assetWarrants exercisable periodClass Of Warrant Or Right Year From Which Warrants Or Rights ExercisableClass of warrant or right year from which warrants or rights exercisable.Business combination event shares issued to holders of equity and convertible note holders.Business Combination Event Shares Issued To Holders of Equity and Convertible Note HoldersBusiness combination event shares issued to holders of equity and convertible note holdersIncrease (Decrease) in Operating Lease LiabilityLease liabilitiesWall Street JournalWall Street Journal [Member]Wall street journal.Fair Value, Net Derivative Asset (Liability) Measured on Recurring Basis, Unobservable Input Reconciliation [Line Items]Operating Lease, Liability, NoncurrentOperating lease liabilities, net of current portionTranche OneTranche One [Member]Tranche One.FederalDomestic Tax Jurisdiction [Member]Debt Instrument, Name [Domain]Additional paid-in capitalAdditional Paid in Capital, Common StockEmbedded derivative liability measured at fair valueEmbedded Derivative, Fair Value of Embedded Derivative LiabilityPercentage of aggregate principal amount of term loan advance to purchase number of common sharesPercentage Of Aggregate Principal Amount Of Term Loan Advance To Purchase Number Of Common SharesPercentage of aggregate principal amount of term loan advance to purchase number of common shares.Convertible Notes - Common Shares IssuedConvertible NotesConvertible Notes [Member]Convertible notes.Redeemable convertible preferred shares at a price per shareSale of Stock, Price Per ShareDebt issuance costs expensed upon issuance of convertible debentures recorded using the fair value optionDebt Issuance Costs Expensed Upon Issuance Of Convertible Debentures Recorded Using The Fair Value OptionDebt issuance costs expensed upon issuance of convertible debentures recorded using the fair value option.Net lossNet lossNet lossLessee, Lease, Description [Table]ExercisedStock options exercisedExercisedExercise of stock options (in shares)Variable Rate [Domain]Research and DevelopmentResearch and Development Expense [Member]Common Share and Preferred Share WarrantsCommon Share And Preferred Share Warrants [Policy Text Block]Common share and preferred share warrants.Operating lease commencement periodOperating Lease Commencement PeriodOperating lease commencement period.Schedule of Carrying Value of Term LoanSchedule of Debt [Table Text Block]Equity Component [Domain]Statistical Measurement [Domain]Document Financial Statement Error Correction [Flag]General and Administrative Expense, TotalGeneral and Administrative ExpenseGeneral and administrativePercentage of price paid in qualified financingPercentage Of Price Paid In Qualified FinancingPercentage of price paid in qualified financing.Short-Term Debt [Line Items]Unrealized gain (loss) on available-for-sale investmentsOther Comprehensive Income (Loss), Available-for-Sale Securities Adjustment, Net of Tax, Portion Attributable to Parent, TotalOther Comprehensive Income (Loss), Available-for-Sale Securities Adjustment, Net of Tax, Portion Attributable to ParentUnrealized loss on available-for-sale investmentsInterest expenseInterest Expense, DebtInterest Expense, Debt, TotalOther expense, netOther expense, netTotal other (income) expense, netOther Nonoperating Income (Expense)Stock option termShare-Based Compensation Arrangement by Share-Based Payment Award, Expiration PeriodForeign exchange rate translation adjustmentFair Value, Net Derivative Asset (Liability) Measured on Recurring Basis, Unobservable Inputs Reconciliation, Gain (Loss) Included in Other Comprehensive Income (Loss)Cybersecurity Risk Materially Affected or Reasonably Likely to Materially Affect Registrant [Text Block]Office FurnitureFurniture and Fixtures [Member]Cybersecurity Risk Management Processes Integrated [Flag]Proceeds from line of creditProceeds from Lines of CreditProceeds from Lines of Credit, TotalNet lossNet Income (Loss), Including Portion Attributable to Noncontrolling InterestNet Income (Loss), Including Portion Attributable to Noncontrolling Interest, TotalCash paid for amounts included in the measurement of operating lease liabilitiesOperating Lease, PaymentsUS Government Corporations and Agencies Securities [Member]Government Agency SecuritiesProceeds from issuance of common shares upon the exercise of stock optionsProceeds from Stock Options ExercisedProceeds from exercise of stock optionsPercentage of tax benefit to be realized for recognition in the income statement.Percentage Of Tax Benefit To Be Realized For Recognition In The Income StatementPercentage of tax benefit to be realized for recognition in the income statementDebt discount, net of accretionDebt Instrument, Unamortized DiscountDebt Instrument, Unamortized Discount, TotalConvertible DebenturesDeferred Tax Assets Convertible DebentureDeferred tax assets convertible debentureOptions unvestedShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Nonvested, Number of SharesShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Nonvested, Number of Shares, Ending BalanceShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Nonvested, Number of Shares, Beginning BalancePayables and Accruals [Abstract]February two thousand twenty four subscription agreements.February Two Thousand Twenty Four Subscription Agreements [Member]February 2024 Subscription AgreementsOtherOtherDeferred Tax Liabilities, OtherAdjustments to Additional Paid in Capital, Warrant IssuedIssuance of warrants in connection with Amended Term LoanTotal commitment amountCommitment AmountCommitment amount.Temporary equity stock issued during the period shares.Temporary Equity Stock Issued During The Period SharesTemporary equity stock issued during the period sharesIssuance of common shares upon cashless exercise of optionsStock Issued During Period Value Upon Cashless Exercise of OptionsStock issued during period value upon cashless exercise of options.Scientific research and experimental development expendituresScientific Research And Experimental Development ExpendituresSR&ED expendituresPrice per unit paid for common shares and warrantsPrice Per Unit Paid for Common Shares and WarrantsPrice per unit paid for common shares and warrants.Prepaid and other current assetsPrepaid Expense and Other Assets, CurrentRisk-free interest rate, MaximumShare-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Risk Free Interest Rate, MaximumTotal aggregate proceedsProceeds from Issuance of Redeemable Convertible Preferred StockCollaborative Arrangement and Arrangement Other than Collaborative [Axis]Class of Stock [Domain]Measurement Input, Preferred Share Price - Class C (CAD)Measurement Input, Share Price [Member]Class C Preferred Share Price (CAD)Total comprehensive lossTotal comprehensive lossComprehensive Income (Loss), Net of Tax, Attributable to ParentCommon Stock, Shares, Outstanding, Ending BalanceCommon Stock, Shares, Outstanding, Beginning BalanceCommon Stock, Shares, OutstandingCommon stock shares outstandingTotal Common Shares outstanding immediately after the Reverse Recapitalization and PIPE FinancingPercentage of repay on closing date amount equal to principal.Percentage Of Repay On Closing Date Amount Equal To PrincipalPercentage of repay on closing date amount equal to principalPurchases of investmentsPayments to Acquire Investments, TotalPayments to Acquire InvestmentsProceeds from trust account in connection with reverse recapitalization.Proceeds From Trust Account in Connection with Reverse RecapitalizationProceeds from FEAC trust account in connection with Reverse RecapitalizationFair Value, off-Balance-Sheet Risks, Disclosure Information [Line Items]Percentage of increase in annual base rentPercentage of Increase in Annual Base RentPercentage of increase in annual base rent.Schedule of Components of Income Tax Expense (Benefit) [Table Text Block]Summary Of Components Of The Provision For (Recovery Of) Income TaxesAccrued interestDebt Instrument, Accrued InterestDebt instrument, accrued interest.R&D expendituresDeferred Tax Asset, In-Process Research and DevelopmentTemporary Equity, Redemption Price Per ShareTemporary equity redemption price per shareAntidilutive Securities [Axis]Financing costsDeferred Tax Assets Financing CostsDeferred tax assets financing costs.Cybersecurity Risk Process for Informing Management or Committees Responsible [Text Block]Cash - PIPE FinancingProceeds from Issuance or Sale of Equity, TotalProceeds from Issuance or Sale of EquityProceeds from PIPE financingSchedule of Common Stock Outstanding Roll Forward [Table Text Block]Summary of Number of Common Shares OutstandingCashForeign (US)Deferred

Foreign Income Tax Expense (Benefit)Class A Initial ClosingClass A Initial Closing [Member]Class A initial closing.Entity Interactive Data CurrentLease expiration dateLease Expiration DateDeferred financing cost current.Deferred Financing Cost CurrentDeferred financing costRight of Use AssetsDeferred Tax Liabilities Right Of Use AssetsDeferred tax liabilities right of use assets.Summary of Net Proceeds from Reverse Recapitalization and PIPE FinancingSummary of Net Proceeds from Reverse Recapitalization and PIPE Financing [Table Text Block]Summary of net proceeds from reverse recapitalization and pipe financing.Marketable Securities [Table]Fair value of related warrantsFair value of warrantsFair Value Of WarrantsFair value of warrants.Accounting Standards Update [Domain]Change in fair valueChange in Fair Value of Debt InstrumentChange in fair value of debt instrument.AccrualsDeferred Tax Assets, Tax Deferred Expense, Reserves and AccrualsDeferred Tax Assets, Tax Deferred Expense, Reserves and Accruals, TotalSummary of Outstanding Principal, Accrued Interest and Unamortized Deferred Financing Costs of Convertible Debentures Recorded on Balance SheetMarketable Securities [Table Text Block]Schedule of Marketable SecuritiesRelated Party Transactions Disclosure [Text Block]Related Party TransactionsStatement of Financial Position Location, Balance [Axis]Statistical Measurement [Axis]Operating lease costOperating Lease, CostTranche ThreeShare-Based Payment Arrangement, Tranche Three [Member]Financial assets, fair valueAssets, Fair Value DisclosureFinancial assetsTotal financial assetsSeries 1 Class C Redeemable Convertible PreferredSeries 1 Class C Redeemable Convertible Preferred [Member]Series 1 class c redeemable convertible preferred.Related and Nonrelated Parties [Domain]Total operating lease costLease, CostTerm LoanTerm Loan [Member]Term loan.Lessee, Operating Lease, Liability, to be Paid, Maturity [Table Text Block]Schedule of Maturities of Operating Lease LiabilitiesNumber of options remain available for grantShare-Based Compensation Arrangement by Share-Based Payment Award, Number of Shares Available for GrantUnrecognized compensation expense weighted-average period of recognitionShare-Based Payment Arrangement, Nonvested Award, Cost Not yet Recognized, Period for RecognitionProceeds from Issuance of Private PlacementProceeds from PIPE financingsEffect of Exchange Rate on Cash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents, Continuing OperationsEffect of exchange rate changes on cashNet deferred tax assets (liability)Net deferred tax assets (liability)Deferred Tax Assets, NetInducement Grants [Member]Inducement Grants [Member]Inducement GrantsResearch and Development ExpensesResearch and Development Expense, Policy [Policy Text Block]Statement of Income Location, Balance [Axis]Short-Term Debt [Table]2023 PlanTwo Zero Two Three Plan [Member]Two zero two three plan.DebentureDebenture [Member]Debenture member.AssetsTotal assetsExpected term (in years)Share-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected TermTax Period [Axis]Schedule of Long-Term Debt Instruments [Table]Foreign (US)Current Foreign Tax Expense (Benefit)Weighted- Average Remaining Contractual Term (in years), Options unvestedShare Based Compensation Arrangement By Share Based Payment Award Options Unvested Weighted Average Remaining Contractual Term1Share based compensation arrangement by share based payment award options unvested weighted average remaining contractual term1.Foreign (US)Income (Loss) from Continuing Operations before Income Taxes, ForeignTotal deferred tax liabilitiesTotal Deferred tax liabilitiesTotal Deferred tax liabilitiesDeferred Tax Liabilities, GrossFair value debt inputs measurement inputDebt Instrument, Measurement InputOffice SpaceOffice Space [Member]Office space.Recently Adopted Accounting Pronouncements and Recently Issued Accounting Pronouncements - Not Yet AdoptedNew Accounting Pronouncements, Policy [Policy Text Block]Entity Address, City or TownAccumulated Other Comprehensive LossAOCI Attributable to Parent [Member]Equity [Abstract]OtherEffective Income Tax Rate Reconciliation, Other Adjustments, PercentAuditor LocationReclassification of Warrants to equity upon consummation of the Reverse RecapitalizationReclassification of Warrants to equity upon consummation of the Reverse RecapitalizationFair Value Measurement with Unobservable Inputs Reconciliation Recurring Basis Liability Reclassification Of Warrants To Equity Upon Consummation Of Reverse RecapitalizationFair value measurement with unobservable inputs reconciliation recurring basis liability reclassification of warrants to equity upon consummation of reverse recapitalization.CANADACanadianSchedule of Estimated Future Principal Payments Due Under the Loan AgreementSchedule of Maturities of Long-Term Debt [Table Text Block]Cybersecurity Risk Materially Affected or Reasonably Likely to Materially Affect Registrant [Flag]License Agreement and Clinical Research Organization [Line Items]License agreement and clinical research organization line items.BalanceBalanceFair Value, Net Derivative Asset (Liability) Measured on Recurring Basis with Unobservable InputsValue of stock and warrant issued during the period.Value of Stock and Warrant Issued During the PeriodValue of stock and warrant issued during the periodBorrowed amountPrincipal amountTerm loans aggregate principal amountLong-Term Debt [Member]Long-term InvestmentsLess transaction costs withheld from cash proceeds on Closing DateTransaction Cost Withheld From Proceeds ReceivedTransaction cost withheld from rroceeds received.Less transaction costs withheld from cash proceeds on Closing DateTranche 3 AdvanceTranche Three Advance [Member]Tranche three advance.ASU 2020-06Accounting Standards Update 2020-06 [Member]Depreciation of property and equipmentDepreciationDepreciation, TotalFair value of sharesShare PriceShare price2023 FinancingTwo Zero Two Three Financing MemberTwo Zero Two Three Financing.Cybersecurity Risk Third Party Oversight and Identification Processes [Flag]Non-Voting Common SharesNonvoting Common Stock [Member]Private PlacementPrivate Placement [Member]Concentration Risk, Credit Risk, Financial Instruments, off-Balance-Sheet RiskOff-balance sheet concentrations of credit risk descriptionShare-Based CompensationShare-Based Payment Arrangement [Text Block]Warrant liability recognized upon issuance of term loanWarrant Liability Recognized Upon Issuance Of Term LoanWarrant liability recognized upon issuance of term loan.Cybersecurity Risk Management Positions or Committees Responsible Report to Board [Flag]Share-Based Compensation Arrangement by Share-Based Payment Award, Number of Shares AuthorizedNumber of shares authorized increasedWeighted-Average Exercise Price, Options vested and not exercisableShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and not Exercisable, Weighted Average Exercise PriceShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and not Exercisable, Weighted Average Exercise PriceSummary of Change in Estimated Fair Value of LiabilitiesFair Value, Measured on Recurring Basis, Gain (Loss) Included in Earnings [Table Text Block]Common shares and warrants on relative fair value, basis price per unit paidReverse Recapitalization Price Per Unit Paid Common Shares And Warrants On Relative Fair Value BasisReverse recapitalization price per unit paid common shares and warrants on relative fair value basis.Debt Securities, Available-for-Sale, Accrued Interest, after Allowance for Credit Loss, Statement of Financial Position [Extensible Enumeration]Other Assets [Member]Fair Value Disclosures [Abstract]Conversion of debenturesEffective Income Tax Rate Conversion Of DebenturesEffective income tax rate conversion of debentures.Number of new warrant issued during the period.Number of New Warrant Issued During the PeriodNumber of new warrant issued during the periodEntity Public FloatWeighted-Average Exercise Price, Forfeited or expiredShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Forfeitures and Expirations in Period, Weighted Average Exercise PriceForbion Growth Sponsor FEAC I B.VForbion Growth Sponsor FEAC I B.V [Member]Forbion Growth Sponsor FEAC I B.V Member.Stock Issued During Period, Value, New IssuesStockIssuedDuringPeriodValueNewIssuesIssuance of common shares, valueExercise of stock optionsStock Issued During Period, Value, Stock Options ExercisedLessee, Lease, Description [Line Items]Liabilities, Current [Abstract]Current liabilities:Issuance of common shares upon exercise of warrants (in shares)Stock issued during period shares warrants exercised.Stock Issued During Period Shares Warrants ExercisedCommon stock issued redemption priceCommon Stock Issued Redemption PriceCommon stock issued redemption price.Liabilities assumed upon Reverse RecapitalizationLiabilities AssumedDocument TypeDocument TypeAccounting Standards Update [Axis]Government Agency SecuritiesUS Government Agencies Debt Securities [Member]Additional reserves of common stock for issuanceAdditional reserves of common stock for issuanceAdditional reserves of common stock for issuance.Title of 12(b) SecurityClass C Second TrancheClass C Second Tranche [Member]Class c second tranche.Cash and cash equivalentsCash and Cash Equivalents, at Carrying ValueCash and Cash Equivalents, at Carrying Value, TotalClass C Redeemable Convertible Preferred SharesClass C Redeemable Convertible Preferred Shares [Member]Class C redeemable convertible preferred shares.Statement of Financial Position Location, Balance [Domain]Lessee, Operating Lease, Liability, to be Paid, Year Five2029Schedule of Components of Operating Lease CostLease, Cost [Table Text Block]Series 4 Class C Redeemable Convertible PreferredSeries 4 Class C Redeemable Convertible Preferred [Member]Series 4 class c redeemable convertible preferred.Cybersecurity Risk Management, Strategy, and Governance [Line Items]Statement of Stockholders' Equity [Abstract]Ending BalanceBeginning BalanceFair Value, Measurement with Unobservable Inputs Reconciliation, Recurring Basis, Liability ValueDocument Fiscal Period FocusConversion and exchange of Old enGene convertible debentures and common share warrants into enGene Holdings common shares and common share warrants in connection with the Reverse Recapitalization (in shares)Conversion and Exchange of Old Convertible Debentures and Common Share Warrants Into New Common Shares and Common Share Warrants in Connection With Reverse Recapitalization SharesConversion and exchange of old convertible debentures and common share warrants into new common shares and common share warrants in connection with reverse recapitalization shares.Research and developmentResearch and Development ExpenseResearch and Development Expense, TotalCapital loss carryforward.Capital Loss CarryforwardCapital lossesOld enGenes WarrantOld enGenes Warrant Holders MemberOld enGenes Warrant Holders MemberMeasurement Input Liquidity Price At Conversion Of Listing Event [Member]Measurement input liquidity price at conversion of listing event.Liquidity price at conversion of listing eventGrantedShares GrantedNumber of share options granted during the periodCommon Stock, Shares Authorized, Unlimited [Fixed List]Common stock shares authorized unlimitedDividends or distributions declared or paidPayments of DividendsPayments of Dividends, TotalConvertible Debentures Embedded Derivative LiabilitiesEmbedded Derivative Financial Instruments [Member]Earliest Tax Year2028Asset Class [Domain]Property and equipmentProperty, Plant and Equipment, GrossProperty, Plant and Equipment, Gross, Ending BalanceProperty, Plant and Equipment, Gross, Beginning BalanceProperty, Plant and Equipment, Gross, TotalDeferred transaction costsDeferred CostsDeferred Costs, TotalSubsequent Event Type [Domain]LeasesLessee, Leases [Policy Text Block]Measurement Input, Expected TermMeasurement Input, Expected Term [Member]Expected time to respective scenariosSchedule of Assumptions Used to Determine Grant-Date Fair Value of Stock OptionsSchedule of Share-Based Payment Award, Stock Options, Valuation Assumptions [Table Text Block]Modification of existing debt.Modification Of Existing DebtModification of existing debtCash proceeds received from the Reverse Recapitalization and PIPE Financing on Closing DateGross Cash Proceeds Received from Reverse Recapitalization and Pipe FinancingGross cash proceeds received from reverse recapitalization and pipe financing.Fair Value, off-Balance-Sheet Risk [Table]Warrants, exercise price per shareClass of Warrant or Right, Exercise Price of Warrants or RightsFinancial Instruments [Domain]Unrealized Gain (Loss), Foreign Currency Transaction, before TaxUnrealized foreign currency (gain) lossesSale of Stock [Axis]Cash flows from investing activitiesNet Cash Provided by (Used in) Investing Activities [Abstract]Expiring term of warrantsClass of Warrant or Right, Date from which Warrants or Rights ExercisableLease expiration month and yearLease Expiration Month and YearLease expiration month and year.RepaymentDebt Instrument, Repaid, PrincipalMarketable Securities, CurrentMarketable securities - short termCash dividends declaredCommon Stock, Dividends, Per Share, DeclaredSeries 3 Class C Redeemable Convertible PreferredSeries 3 Class C Redeemable Convertible Preferred [Member]Series 3 class c redeemable convertible preferred.Income TaxesIncome Tax Disclosure [Text Block]Summary Of Reconciliation Of Company's Statutory Income Tax RateSchedule of Effective Income Tax Rate Reconciliation [Table Text Block]Cybersecurity Risk Management, Strategy, and Governance [Abstract]If Interim Milestone Achieved and No DefaultIf Interim Milestone Achieved and No Default [Member]If interim milestone achieved and no default.Weighted- Average Remaining Contractual Term (in years), Options vested and not exercisableShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and not Exercisable, Weighted Average Remaining Contractual TermShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and not Exercisable, Weighted Average Remaining Contractual Term.Amount of convertible debentures and warrantsConvertible Debentures And WarrantsConvertible debentures and warrants.Settlement of derivative liability in accordance with repayment and conversion of convertible debentures upon the consummation of the Reverse RecapitalizationFair Value, Net Derivative Asset (Liability) Measured on Recurring Basis, Unobservable Inputs Reconciliation, SettlementsCredit Facility [Domain]Conversion of Convertible Debentures upon Reverse RecapitalizationConversion Of Convertible Debentures Upon Reverse RecapitalizationConversion of convertible debentures upon reverse recapitalization.Increase in number of share reserved for future issuance in the beginning of the yearShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Period Increase (Decrease)Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Period Increase (Decrease), TotalInvestissement QuebecInvestissement Quebec [Member]Investissement Quebec Member.OtherOther Accrued Liabilities, CurrentAccounts payableIncrease (Decrease) in Accounts PayableIncrease (Decrease) in Accounts Payable, TotalDeferred tax liabilities:Deferred Tax Liabilities, Net [Abstract]Lab equipmentLab Equipment [Member]Lab equipment.Liabilities and Equity [Abstract]Liabilities and Shareholder's equityDocument Period End DatePeriod End DateInvestment tax creditsInvestment Tax CreditNet Cash Provided by (Used in) Financing ActivitiesNet cash provided by financing activitiesSecurities Financing Transaction [Axis]Common shares and common share warrants issued upon Reverse Recapitalization and PIPE Financing, net of issuance costs of $11.1 millionCommon Shares and Common Share Warrants Issued Upon Reverse Recapitalization and Pipe Financing ValueCommon shares and common share warrants issued upon reverse recapitalization and pipe financing value.End of term fee percentageEnd of Term Fee PercentageEnd of term fee percentage.Accrued interest percentageDebt Instrument Accrued Interest RateDebt instrument accrued interest rate.ICFR Auditor Attestation FlagEffective income tax rateEffective Income Tax Rate Reconciliation, PercentStockholders' Equity Note [Abstract]Conversion and exchange of Old enGene convertible debentures and common share warrants into enGene Holdings common shares and common share warrants in connection with the Reverse RecapitalizationConversion and Exchange of Old Convertible Debentures and Common Share Warrants Into New Common Shares and Common Share Warrants in Connection With Reverse Recapitalization ValueConversion and exchange of old convertible debentures and common share warrants into new common shares and common share warrants in connection with reverse recapitalization value.Shares excluded from computation of diluted net loss per shareAntidilutive Securities Excluded from Computation of Earnings Per Share, AmountDate of closed private placementDate of closed private placement.Date of Closed Private PlacementWarrant liabilities recognized upon issuanceFair Value Measurement with Unobservable Inputs Reconciliation Recurring Basis Liability Warrant Liability Recognized Upon IssuanceFair value measurement with unobservable inputs reconciliation recurring basis liability warrant liability recognized upon issuance.Class B common sharesClass B Common SharesCommon Class B [Member]Warrants exercisable periodClass Of Warrant Or Rights Number Of Days From Which Warrants Or Rights ExercisableClass of warrant or rights number of days from which warrants or rights exercisable.Settlement of April 2023 Notes through the issuance of May 2023 Notes and warrantsDebt Conversion, Converted Instrument, AmountLessee, Operating Lease, Liability, to be Paid, after Year FiveThereafterOptions vested and not exercisableShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and not Exercisable, NumberShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and not Exercisable, Number.Transaction costs related to issuance of notesTransaction Costs Related To Issuance Of NotesTransaction costs related to issuance of notes.Fair Value, Net Derivative

Asset (Liability) Measured on Recurring Basis, Unobservable Input Reconciliation [Table]April 2023 NotesApril Twenty Twenty Three Notes [Member]April Twenty Twenty Three Notes Member.Total income tax expense (benefit)Income Tax Expense (Benefit)Provision for (recovery of) income taxesMay 2023 NotesMay Two Thousand Two Three Notes MemberMay Two Thousand Two Three Notes.Loss on the disposal of property and equipmentGain (Loss) on Disposition of Property Plant Equipment, TotalGain (Loss) on Disposition of Property Plant EquipmentReverse recapitalization price per unit paid common shares and warrantsReverse Recapitalization Price Per Unit Paid Common Shares And WarrantsReverse recapitalization price per unit paid common shares and warrants.Trading SymbolVariable Rate [Axis]Equity, Attributable to ParentEnding balanceBeginning balanceTotal shareholder's equityLoss on extinguishment of convertible debenturesLoss on extinguishment of convertible debenturesGain (Loss) On Extinguishment Of Convertible DebenturesGain (loss) on extinguishment of convertible debentures.Class C Inital ClosingClass C Initial Closing [Member]Class C initial closing.2024 PIPE investors.Two Thousand Twenty Four PIPE Investors [Member]2024 PIPE InvestorsConversion of Preferred Shares upon Reverse RecapitalizationConversion Of Preferred Shares Upon Reverse RecapitalizationConversion of preferred shares upon reverse recapitalization.Total deferred tax assetsTotal deferred tax assetsDeferred Tax Assets, GrossLong-Lived Tangible Asset [Axis]Warrants outstandingClass of Warrant or Right, OutstandingClass B Intial ClosingClass B Initial Closing [Member]Class B initial closing.Share-Based CompensationShare-Based Payment Arrangement [Policy Text Block]Conversion priceDebt Instrument, Convertible, Conversion PriceDerivative Instrument [Axis]Research and development investment tax creditsResearch And Development Investment Tax CreditsResearch and development investment tax credits.Initial aggregate amount that company agreed to sellSale of Stock, Number of Shares Issued in TransactionRelated Party Transactions [Abstract]License Agreement and Clinical Research Organization [Abstract]License Agreement and Clinical Research OrganizationVariable operating lease costVariable Lease, CostProperty, Plant and Equipment [Table]Cybersecurity Risk Management, Strategy, and Governance [Table]GoodwillGoodwill, Ending BalanceGoodwill, Beginning BalanceGoodwill, TotalBDC NotesBDC Notes [Member]BDC Notes Member.Change in Accounting Principle, Accounting Standards Update, AdoptedChange in Accounting Principle, Accounting Standards Update, Adopted [true false]Unrecognized compensation expenseShare-Based Payment Arrangement, Nonvested Award, Cost Not yet Recognized, AmountShare-Based Payment Arrangement, Nonvested Award, Cost Not yet Recognized, Amount, TotalPercentage of principalPercentage Of Principal AmountPercentage Of Principal Amount.Cybersecurity Risk Management Expertise of Management Responsible [Text Block]Summary of Share-based Compensation ExpenseShare-Based Payment Arrangement, Expensed and Capitalized, Amount [Table Text Block]Measurement Input, Discount Rate [Member]Discount rateOld enGenes Equity and Convertible NoteOld enGenes Equity and Convertible Note Holder MemberOld enGenes Equity and Convertible Note Holder.Repayments of term loan principalRepayments of term loan principalRepayments of term loan principal.Measurement Input Type [Axis]Total deferred tax expense (benefit)Deferred Income Tax Expense (Benefit)Deferred Income Tax Expense (Benefit), TotalGeographical [Axis]Debt Securities, Available-for-Sale, Accumulated Gross Unrealized Loss, before TaxUnrealized Holdings LossesLeases [Abstract]Number of securities held.Number of Securities HeldNumber of securities heldLab EquipmentEquipment [Member]Use of EstimatesUse of Estimates, Policy [Policy Text Block]Issuance of Common Shares in Connection With Pipe Financing ValueIssuance of common shares in connection with pipe financing value.Issuance of common shares in connection with PIPE Financing, net of issuance costsCash and Cash EquivalentsCash and Cash Equivalents, Policy [Policy Text Block]Conversion and exchange of redeemable convertible preferred stock into common shares in connection with the Reverse RecapitalizationStock Issued During Period, Value, Conversion of Convertible SecuritiesPercentage of prepayment premium of principal amount outstanding prior to twenty-four monthsPercentage of Prepayment Premium of Principal Amount Outstanding Prior to Twenty Four MonthsPercentage of prepayment premium of principal amount outstanding prior to twenty four months.Severance AgreementSeverance Agreement.Severance Agreement [Member]Share-based compensation expenseAPIC, Share-Based Payment Arrangement, Option, Increase for Cost RecognitionClass A Second TrancheClass A Second Tranche [Member]Class a second tranche.Schedule of Shares Reserved for Future Issuance Under the PlanSchedule of Shares Reserved For Future Issuance Under The Plan Table Text BlockSchedule of shares reserved for future issuance under the plan.Class of Stock [Line Items]Measurement Input, Expected VolatilityVolatilityMeasurement Input, Price Volatility [Member]Expected volatility, MinimumShare-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Volatility Rate, MinimumLessee Disclosure [Abstract]Expected dividend yieldShare-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Dividend RateMarketable securitiesMarketable Securities, Policy [Policy Text Block]Net cash proceeds from the Reverse Recapitalization and PIPE FinancingNet Cash Proceeds Received from Reverse Recapitalization and Pipe Financing.Net cash proceeds received from reverse recapitalization and pipe financing.Fair value debt inputs, termFair Value Debt Inputs, TermFair value debt inputs, term.Security Exchange NameShort term marketable securitiesShort Term Marketable Securities [Member]Short Term Marketable SecuritiesCounterparty Name [Domain]Deferred Tax Assets, Tax Credit CarryforwardsDeferred Tax Assets, Tax Credit Carryforwards, TotalInvestment tax credits, netBusiness Acquisition, Acquiree [Domain]Total operating expensesOperating ExpensesMeasurement Input, Risk-free Interest RateMeasurement Input, Risk Free Interest Rate [Member]Accrued interest receivable written off.Accrued Interest Receivable Written OffAccrued interest receivable written offIf Interim Milestone and Certain Clinical Milestones Achieved and No DefaultIf Interim Milestone and Certain Clinical Milestones Achieved and No Default [Member]If interim milestone and certain clinical milestones achieved and no default.Long-Lived Tangible Asset [Domain]Class of Stock [Axis]Accrued interest related to unrecognized tax benefitsUnrecognized Tax Benefits, Interest on Income Taxes AccruedLess: Accumulated depreciation and amortizationAccumulated Depreciation, Depletion and Amortization, Property, Plant, and EquipmentAccumulated Depreciation, Depletion and Amortization, Property, Plant, and Equipment, Ending BalanceAccumulated Depreciation, Depletion and Amortization, Property, Plant, and Equipment, Beginning BalanceAccumulated Depreciation, Depletion and Amortization, Property, Plant, and Equipment, TotalLegal Entity:Legal Entity [Axis]Fair Value MeasurementsFair Value Disclosures [Text Block]Lessee, Operating Lease, Liability, to be Paid, Year Three2027Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Grants in Period, Weighted Average Grant Date Fair ValueWeighted-average grant-date fair value per share of share options grantedShares convertedConversion of Stock, Shares ConvertedSubsequent EventSubsequent Event [Member]Maximum [Member]MaximumLiabilities and EquityTotal liabilities and shareholder's equityIntangible assetsIntangible Assets, Gross (Excluding Goodwill)Intangible Assets, Gross (Excluding Goodwill), TotalProbability of Qualified FinancingMeasurement Input Probability Of Qualified Financing [Member]Measurement input probability of qualified financing.Reverse Recapitalization [Table]Reverse recapitalization.Loss on extinguishment of convertible debenturesGain (Loss) on Extinguishment of DebtGain (Loss) on Extinguishment of Debt, TotalLoss on extinguishment of debtGain on extinguishment of debtOperating lease right of use assetsOperating Lease, Right-of-Use AssetIssued options fully vestedShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested, Number of SharesSupplemental cash flow information:Supplemental Cash Flow Information [Abstract]Financial liabilities, fair valueFinancial liabilitiesFinancial Liabilities Fair Value DisclosureFinancial Liabilities Fair Value Disclosure, TotalPrime RatePrime Rate [Member]Earnings Per Share, Diluted, TotalEarnings Per Share, DilutedNet loss per share of common shares, dilutedLeasehold ImprovementsLeasehold Improvements [Member]Preferred Share Warrant LiabilitiesPreferred share warrant liabilities.Preferred Share Warrant Liabillities [Member]Entity Ex Transition PeriodCommon shares and common share warrants issued upon Reverse Recapitalization and PIPE Financing, net of issuance costs of $11.1 million (in shares)Common Shares and Common Share Warrants Issued Upon Reverse Recapitalization and Pipe Financing SharesCommon shares and common share warrants issued upon reverse recapitalization and pipe financing shares.Total liabilitiesLiabilitiesLiabilities, TotalOffering expensesPayment of Financing and Stock Issuance Costs, TotalPayment of Financing and Stock Issuance CostsPayment-in-kind interest ratePaid-in-kind Interest PercentagePaid-in-kind interest percentage.Common stock voting rightsCommon Stock, Voting RightsFair Value Hierarchy and NAV [Domain]Phase II Clinical Trial [Member]Phase II Clinical TrialTotal current assetsAssets, CurrentTotal current assetsNet Cash Provided by (Used in) Investing ActivitiesNet cash used in investing activitiesStock Issued During Period, Shares, New IssuesNumber of new stock issued during the periodIssuance of common sharesWeighted-Average Exercise Price, Options unvestedExercise priceShare-Based Compensation Arrangement by Share-Based Payment Award, Option, Nonvested, Weighted Average Exercise PriceShare-Based Compensation Arrangement by Share-Based Payment Award, Option, Nonvested, Weighted Average Exercise Price, Ending BalanceShare-Based Compensation Arrangement by Share-Based Payment Award, Option, Nonvested, Weighted Average Exercise Price, Beginning BalancePermanent differencesEffective Income Tax Rate Reconciliation, Nondeductible Expense, PercentEffective Income Tax Rate Reconciliation, Nondeductible Expense, Percent, TotalEstimated Useful LifeProperty Plant And Equipment Estimated Useful LiveProperty plant and equipment estimated useful live.Deduction per 20(1)€Deferred Tax Assets DeductionDeferred tax assets deduction.Valuation allowanceEffective Income Tax Rate Reconciliation, Change in Deferred Tax Assets Valuation Allowance, PercentOptions vesting periodShare-Based Compensation Arrangement by Share-Based Payment Award, Award Vesting PeriodAward vesting periodOperating lease, option to extendLessee, Operating Lease, Existence of Option to Extend [true false]Aggregate Intrinsic Value, Options vested and not exercisableShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and not Exercisable, Aggregate Intrinsic ValueShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and not Exercisable, Aggregate Intrinsic Value.Investment tax credits receivableInvestment Tax Credits ReceivableInvestment tax credits receivable.Entity Filer CategoryShares issued in exchange of debt instrumentDebt Conversion, Converted Instrument, Shares IssuedAccrued penalties related to unrecognized tax benefitsUnrecognized Tax Benefits, Income Tax Penalties AccruedCommon shares percentage.Common Shares PercentageAggregate number of common shares outstanding percentageProperty and equipmentDeferred Tax Assets, Property, Plant and EquipmentProperty, Plant and Equipment [Abstract]Class of Warrant or Right, Number of Securities Called by Each Warrant or RightClass of warrants or rights number of shares covered by each warrant or rightOperating lease extended termLessee, Operating Lease, Extended TermLessee, operating lease, extended term.Net loss attributable to common shareholders, dilutedNet loss attributable to common stockholders, dilutedNet loss attributable to common stockholders, dilutedNet Income (Loss) Available to Common Stockholders, DilutedNet Income (Loss) Available to Common Stockholders, Diluted, TotalFair Value of Common ShareMeasurement Input, Conversion Price [Member]Fair value of common share at conversion of listing eventCurrent Fiscal Year End DateFair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]Property and EquipmentProperty, Plant and Equipment, Policy [Policy Text Block]Lessee, Operating Lease, Liability, Undiscounted Excess AmountLess: InterestLess: InterestTotal share-based compensation expenseShare-based compensation expenseShare-Based Payment Arrangement, Noncash ExpenseShare-Based Payment Arrangement, Noncash Expense, TotalSummary of Estimated Useful Life of Each AssetSchedule Of Estimated Useful Lives Of Property Plant And Equipment [Table Text Block]Schedule of estimated useful lives of property, plant and equipment.Aggregate Intrinsic Value, OutstandingShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Intrinsic ValueOffice and Lab SpaceOffice and Lab Space [Member]Office and lab space.Related and Nonrelated Parties [Axis]Debt Securities, Available-for-Sale, Accrued Interest, after Allowance for Credit Loss, TotalDebt Securities, Available-for-Sale, Accrued Interest, after Allowance for Credit LossAccrued interest receivableRegistrant NameEntity Registrant NameOld hercules warrants.Old Hercules Warrants [Member]Old Hercules WarrantsFormer chief executive officer.Former Chief Executive Officer [Member]Former CEOSchedule of Share-Based Compensation Arrangements by Share-Based Payment Award [Table]Net Loss Per ShareEarnings Per Share [Text Block]Term loan maturity dateMaturity dateDebt Instrument, Maturity DateEntity Emerging Growth CompanyForeign exchange rate translation adjustmentFair Value Measurement with Unobservable Inputs Reconciliation Recurring Basis Liability Foreign Exchange Rate Translation AdjustmentFair value measurement with unobservable inputs reconciliation recurring basis liability foreign exchange rate translation adjustment.Numerator:Net Income (Loss) Available to Common Stockholders, Basic [Abstract]Accounting Standards Update 2016-13 [Member]ASU 2016-13Money Market Funds [Member]Money Market FundsWeighted-average number of common shares used in net loss per share, basicWeighted Average Number of Shares Outstanding, Basic, TotalWeighted Average Number of Shares Outstanding, BasicWeighted-average common shares outstanding, basicVesting [Domain]Merger agreement dateBusiness Acquisition, Date of Acquisition AgreementRepayment of aggregate amountSettlement upon the consummation of the Reverse RecapitalizationRepayment of convertible debenturesRepayment of convertible debenturesRepayments of Convertible DebtExpected volatility, MaximumShare-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Volatility Rate, MaximumConvertible Debenture Embedded Derivative LiabilitiesDerivatives, Embedded Derivatives [Policy Text Block]Common stock capital shares reserved for remaining future issuance.Common Stock Capital Shares Reserved for Remaining Future IssuanceCommon stock capital shares reserved for remaining future issuanceIssuanceNotes IssuedEstimated Useful LifeProperty, Plant and Equipment, Useful LifeProceeds from Issuance of Common StockAggregate gross proceeds of common stockFebruary PIPE financing.February PIPE Financing [Member]February PIPE FinancingConversion ratioPreferred Stock, Convertible, Conversion RatioLevel 1Fair Value, Inputs, Level 1 [Member]Repayments of convertible notes and warrantsRepayments Of Convertible Notes and WarrantsRepayments of convertible notes and warrants.Percentage of facility charge on amount borrowedPercentage of Facility Charge on Amount BorrowedPercentage of facility charge on amount borrowed.Debt Disclosure [Abstract]Fair Value, Net Derivative Asset (Liability), Recurring Basis, Unobservable Input Reconciliation, Gain (Loss), Statement of Income or Comprehensive Income [Extensible Enumeration]Weighted-Average Exercise Price, Options vested and exercisableShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and Expected to Vest, Outstanding, Weighted Average Exercise PriceDocuments Incorporated by ReferenceDocuments Incorporated by Reference [Text Block]Accrued research and development expensesAccrued Research And Development Expense CurrentAccrued research and development expenses current.Exercise priceExercise price of options grantedWeighted-Average Exercise Price, GrantedPercentage of prepayment premium of principal amount outstanding prior to maturity datePercentage of Prepayment Premium of Principal Amount Outstanding Prior to Maturity DatePercentage of prepayment premium of principal amount outstanding prior to maturity date.Reclassification of warrant liability to equity upon Reverse RecapitalizationReclassification of warrant liability to equity upon Reverse RecapitalizationReclassification of warrant liability to equity upon reverse recapitalization.Financial Instrument [Axis]License Agreement and Clinical Research OrganizationLicense agreement and clinical research organizationWeighted- Average Remaining Contractual Term (in years), OutstandingShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Weighted Average Remaining Contractual TermNet Loss Per ShareEarnings Per Share, Policy [Policy Text Block]Remaining shares reserved for future issuance under the equity plansShares Reserved For Future Issuance Under the Equity Plans [Member]Shares reserved for future issuance under the equity plans.Convertible DebenturesDebt, Policy [Policy Text Block]Merger Agreement [Member]Merger agreement.Transition services for consulting fee per hour.Transition Services For Consulting

Fee Per HourTransition services for consulting fee per hourGeneral and AdministrativeGeneral and Administrative Expense [Member]2022 NotesTwenty Twenty Two Notes [Member]Twenty Twenty Two Notes Member.Payments of issuance costs associated with the pipe financing.Payments Of Issuance Costs Associated With The Pipe FinancingPayments of issuance costs associated with the 2024 PIPE FinancingsClass B Third TrancheClass B Third Tranche [Member]Class b third tranche.Share-Based Payment Arrangement [Abstract]Deferred Tax Assets, Capital Loss CarryforwardsCapital loss carryforwardsOctober two thousand twenty four subscription agreements.October Two Thousand Twenty Four Subscription Agreements [Member]October 2024 Subscription AgreementsCommon stock, value issuedStock Issued During Period, Value, AcquisitionsCybersecurity Risk Role of Management [Text Block]Tranche ThreeTranche Three [Member]Tranche three.Percentage of price per sharePercentage Of Price Per SharePercentage of price per share.Aggregate Fair ValueDebt Securities, Available-for-SaleAggregate Fair ValueAccounting Policies [Abstract]Class C Preferred SharesSeries C Preferred Stock [Member]Summary of Stock Option ActivityShare-Based Payment Arrangement, Option, Activity [Table Text Block]Income Tax Disclosure [Abstract]Marketable Securities, NoncurrentMarketable securities - long termSummary of Cash Paid for Amounts Included in the Measurement of the Operating Lease LiabilitiesSummary of Cash Paid for Amounts Included in Measurement of Operating Lease Liabilities [Table Text Block]Summary of cash paid for amounts included in measurement of operating lease liabilities.Equity, Attributable to Parent [Abstract]Shareholders' equity:Initial maturity termDebt Instrument Initial Maturity TermDebt instrument initial maturity term.Measurement Input, Exercise Price - Class C (CAD)Measurement Input, Exercise Price [Member]Statement [Table]Segment InformationSegment Reporting, Policy [Policy Text Block]Summary of Property and EquipmentProperty, Plant and Equipment [Table Text Block]Lease LiabilityDeferred Tax Assets Lease LiabilityDeferred tax assets lease liabilityDebt Issuance CostsDebt Issuance Costs [Policy Text Block]Debt issuance costs.Stock options vesting service periodShare-Based Compensation Arrangement by Share-Based Payment Award, Award Requisite Service PeriodWeighted- Average Remaining Contractual Term (in years), Options vested and exercisableShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and Expected to Vest, Outstanding, Weighted Average Remaining Contractual TermSubsequent Event [Table]Class B Second TrancheClass B Second Tranche [Member]Class b second tranche.Employee entitled for continued pay and health insurance benefits.Employee entitled for continued pay and health insurance benefitsEmployee entitled for continued pay and health insurance benefitsChange in fair value of warrant liabilitiesChange in fair value of warrant liabilitiesFair Value Adjustment of WarrantsEntity File NumberNet increase in cash and cash equivalentsCash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents, Period Increase (Decrease), Including Exchange Rate EffectEarnings Per Share [Abstract]Warrants exercisable periodWeighted average expected life (in years)Warrants, contractual termState taxes, net of federal benefitEffective Income Tax Rate Reconciliation, State and Local Income Taxes, PercentStatement of Financial Position [Abstract]Initial maturity dateDebt Instrument Initial Maturity DateDebt instrument initial maturity date.Entity Incorporation, Date of IncorporationDate of incorporationOperating Income (Loss)Loss from operationsLong-Term Debt, Maturity, Year One2025Shares issued, price per shareShares Issued, Price Per ShareQuoted market price of public warrantsQuoted Market Price of Public WarrantsQuoted market price of public warrants.Expected volatilityShare-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Volatility RateAccrued income tax payableAccrued Income Taxes, CurrentCommon Stock, No Par ValueCommon stock no par valueEntity Shell CompanyTranche 2 Advance Subject to Achievement of Specified Interim MilestoneTranche Two Advance Subject to Achievement of Specified Interim Milestone [Member]Tranche two advance subject to achievement of specified interim milestone.Professional feesAccrued Professional Fees, CurrentAssumptions Used to Determine Fair Value of LiabilitiesFair Value Measurement Inputs and Valuation Techniques [Table Text Block]Accrue interest rateEffective interest rate of outstanding debtDebt Instrument, Interest Rate, Effective PercentageEntity Tax Identification NumberAssets [Abstract]AssetsClass of Warrant or Right [Domain]Fair Value Measurements of Financial InstrumentsFair Value of Financial Instruments, Policy [Policy Text Block]Related party transaction amountRelated Party Transaction, Amounts of Transaction2024 Subscription agreements.2024 Subscription Agreements2024 Subscription Agreements [Member]Entity Current Reporting StatusNet loss attributable to common shareholders, basicNet loss attributable to common stockholders, basicNet loss attributable to common stockholders, basicNet loss attributable to common stockholders, basicNet Income (Loss) Available to Common Stockholders, BasicSchedule of Fair Value Hierarchy for Financial Liabilities Measured at Fair ValueFair Value, Liabilities Measured on Recurring Basis [Table Text Block]Debt Securities, Available-for-Sale, Realized Gain (Loss), TotalDebt Securities, Available-for-Sale, Realized Gain (Loss)Realized gains or losses on sale or maturity of available-for-sale securitiesExchange ratioReverse Recapitalization Exchange RatioReverse recapitalization exchange ratio.Computer SoftwareSoftware Development [Member]Property and Equipment, NetProperty, Plant and Equipment Disclosure [Text Block]Long-Term Debt, Type [Axis]Subsequent Events [Abstract]Payment of reverse recapitalization and pipe financing costs.Payment Of Reverse Recapitalization And Pipe Financing CostsPayment of Reverse Recapitalization and PIPE Financing costsGeographical [Domain]Document Fiscal Year FocusPhase I Clinical Trial [Member]Phase I Clinical TrialChange in Accounting Principle, Accounting Standards Update, Adoption DateChange in Accounting Principle, Accounting Standards Update, Adoption DateTranche TwoShare-Based Payment Arrangement, Tranche Two [Member]Vesting on Remaining YearsPreferred shares, no par value; unlimited shares authorized, zero shares issued and outstanding as of October 31, 2023, and 2022.Preferred Stock, Value, IssuedForfeited or expiredForfeited or expiredShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Forfeitures and Expirations in PeriodShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Forfeitures and Expirations in Period, TotalFixed assets included in accrued expenses and accounts payableCapital Expenditures Incurred but Not yet PaidCash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents, Including Disposal Group and Discontinued Operations, TotalCash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents, Including Disposal Group and Discontinued OperationsCash and cash equivalents at end of periodCash and cash equivalents at beginning of periodNo uncertain tax positionsTax Adjustments, Settlements, and Unusual ProvisionsPeriod within loan disbursements to be madePeriod Within Loan Disbursements to be MadePeriod within loan disbursements to be made.Business Acquisition [Axis]City Area CodeBusiness combination event shares issued on exchange of common share warrants.Business combination event shares issued on exchange of common share warrantsBusiness Combination Event Shares Issued on Exchnage of Common Share WarrantsWarrants outstanding, measurement inputWarrants and Rights Outstanding, Measurement InputTotal current liabilitiesTotal current liabilitiesLiabilities, CurrentWarrants, maturity periodWarrants And Rights Outstanding Maturity PeriodWarrants and rights outstanding maturity period.Derivative Contract [Domain]Total accrued expenses and other current liabilitiesAccrued expenses and other current liabilitiesAccrued Liabilities and Other LiabilitiesLine of Credit Facility, Lender [Domain]Effective Income Tax Rate Reconciliation, at Federal Statutory Income Tax Rate, PercentIncome at Canadian statutory ratePreferred Share WarrantsPreferred Share Warrants [Member]Preferred share warrants.Aggregate amount of base rental paymentsAggregate amount of base rental payments.Aggregate Amount Of Base Rental PaymentsConversion and exchange of redeemable convertible preferred stock into common shares in connection with the Reverse Recapitalization (in shares)Stock Issued During Period, Shares, Conversion of Convertible SecuritiesOrganization, Consolidation and Presentation of Financial Statements [Abstract]Local Phone NumberNew convertible debt.New Convertible Debt [Member]New Convertible Debt [Member]Antidilutive Securities Excluded from Computation of Earnings Per Share [Line Items]Payment to NTC upon assigning the License AgreementPayment On Assigning License to Third PartyPayment on assigning license to third partyOld enGenes Share OptionOld enGenes Share Option Holders MemberOld enGenes Share Option Holders.Warrants to Purchase Redeemable Convertible Preferred SharesWarrants to purchase redeemable convertible preferred sharesWarrants to Purchase Redeemable Convertible Preferred Shares [Member]Warrants to purchase redeemable convertible preferred shares.Cash dividend paidCommon Stock, Dividends, Per Share, Cash PaidIncome Tax Jurisdiction [Axis]Proceeds from exercises of warrantsProceeds from Warrant ExercisesProceeds from exercise of common share warrantsIncome Tax, Policy [Policy Text Block]Income TaxesTerm loan reduced annual interest rateDebt Instrument, Interest Rate, Increase (Decrease)Summary of Loss Before Provision for Income TaxesSchedule of Income before Income Tax, Domestic and Foreign [Table Text Block]Commitments and Contingencies Disclosure [Abstract]Preferred Stock, as convertedConvertible Preferred Stock [Member]Debt issuance costsDebt Issuance Costs, NetDebt Issuance Costs, Net, TotalTerm loan advance.Term Loan Advance [Member]Loan AdvanceOctober PIPE financing.October PIPE Financing [Member]October PIPE FinancingDebt Securities, Available-for-Sale, Amortized CostAmortized CostAmortized CostSummary Of Net Deferred Income TaxSchedule of Deferred Tax Assets and Liabilities [Table Text Block]Acquirer.Acquirer [Axis]Operating Lease, Liability, CurrentOperating lease liabilities, currentAssets transfers or reclassifications out of level 3Fair Value, Measurement with Unobservable Inputs Reconciliation, Recurring Basis, Asset, Transfers out of Level 3Non-cash lease expenseNon Cash Lease ExpensesNon cash lease expenses.Foreign currency translation adjustmentForeign currency translation adjustmentOther Comprehensive Income (Loss), Foreign Currency Transaction and Translation Adjustment, Net of TaxOther Comprehensive Income (Loss), Foreign Currency Transaction and Translation Adjustment, Net of Tax, TotalIncome Tax Jurisdiction [Domain]Interest rateDebt Instrument, Interest Rate, Stated PercentageAccrue interest rate percentageFEACFEAC.FEAC [Member]FEAC [Member]Aggregate amount of shares exchangedConvertible Preferred Stock, Shares Issued upon ConversionAccumulated DeficitRetained Earnings [Member]Purchases of property and equipmentPayments to Acquire Property, Plant, and EquipmentPayments to Acquire Property, Plant, and Equipment, TotalDeferred Transaction CostsDeferred Policy Acquisition Costs, Policy [Policy Text Block]Evergreen provision.Evergreen Provision [Member]Evergreen ProvisionDocument Transition ReportCash equivalents and short-term investments.Cash Equivalents and Short-term Investments [Member]Cash Equivalents and Short-term InvestmentsSecurities Financing Transaction [Domain]Convertible Debentures.Convertible DebenturesConvertible Debentures DisclosureTextBlockPercentage of common stock value on date of grantShare-Based Compensation Arrangement by Share-Based Payment Award, Purchase Price of Common Stock, PercentLessee, Operating Lease, Liability, to be Paid, Year Two2026Common Shares Issued to Pipe InvestorsCommon Shares Issued to Pipe Investors [Member]Common shares issued to pipe investors.Antidilutive Security, Excluded EPS Calculation [Table]Foreign rate differentialEffective Income Tax Rate Reconciliation, Foreign Income Tax Rate Differential, PercentTranche 1 AdvanceTranche One Advance [Member]Tranche one advance.May 2023 FinancingMay Twenty Twenty Three Financing [Member]May Twenty Twenty Three Financing Member.Weighted-Average Exercise Price, ExercisedShare-Based Compensation Arrangements by Share-Based Payment Award, Options, Exercises in Period, Weighted Average Exercise PriceFair Value, Liabilities Measured on Recurring Basis, Unobservable Input Reconciliation [Line Items]Risk of Concentrations of Credit and Off-Balance Sheet RiskConcentration Risk, Credit Risk, Policy [Policy Text Block]Debt discount and issuance costsDebt Instrument, Unamortized Discount (Premium) and Debt Issuance Costs, NetDebt Instrument, Unamortized Discount (Premium) and Debt Issuance Costs, Net, TotalAuditor Firm IDMinimumMinimum [Member]CEO Transition Agreement.CEO Transition Agreement [Member]CEO Transition AgreementCommon SharesCommon Stock [Member]Long-Term Debt, Maturity, Year Two2026Accrued Expenses and Other Current LiabilitiesAccounts Payable and Accrued Liabilities Disclosure [Text Block]Aggregate Intrinsic Value, Options vested and exercisableShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and Expected to Vest, Outstanding, Aggregate Intrinsic ValueLoss on extinguishmentEmbedded Derivative, Loss on Embedded DerivativeConversion and exchange of redeemable convertible preferred shares into common shares in connection with the Reverse RecapitalizationConversion and Exchange of Temporary Equity Into Common Shares in Connection With Reverse Recapitalization ValueConversion and exchange of temporary equity into common shares in connection with reverse recapitalization value.Additional Paid in CapitalAdditional Paid-in Capital [Member]Percentage of issuance of common stock optionsPercentage of issuance of common stock optionsPercentage of issuance of common stock optionsEntity Well-known Seasoned IssuerAdjustments to Reconcile Net Income (Loss) to Cash Provided by (Used in) Operating Activities [Abstract]Adjustments to reconcile net loss to net cash used in operating activitiesOptions to purchase common sharesShare Based Compensation Arrangement By Share Based Payment Award Option to Purchase Common SharesShare based compensation arrangement by share based payment award option to purchase common shares.Fair value using the quoted market price for FEAC's common shareEmbedded derivative liability measurement inputEmbedded Derivative Liability, Measurement InputStatement of Income Location, Balance [Domain]Lessee, Operating Lease, Liability, to be Paid, Year One2025Other assetsOther Assets, NoncurrentThe Old PlansThe Old Plans [Member]The old plans.Change in fair value of convertible debenture embedded derivative liabilitiesChange in fair value of convertible debenture embedded derivative liabilitiesChange In Fair Value Of Convertible Debenture Embedded Derivative LiabilitiesChange in fair value of convertible debenture embedded derivative liabilities.Fair value of common shares and exercise price of options, MaximumShare Based Compensation Arrangement By Share Based Payment Award Fair Value of Common Shares and Exercise Price of Options MaximumShare based compensation arrangement by share based payment award fair value of common shares and exercise price of options maximum.Fair Value, Measurement with Unobservable Inputs Reconciliation, Liability, Transfers out of Level 3Liabilities transfers or reclassifications out of level 3Amount of monthly fee for consulting periodAmount of monthly fee for consulting period.Amount Of Monthly Fee For Consulting PeriodIssuance costsStock Issuance CostsStock issuance costs.Hercules WarrantsHercules Warrants [Member]Hercules warrants.Domestic (Canada)Current Federal, State and Local, Tax Expense (Benefit)Current Federal, State and Local, Tax Expense (Benefit), TotalChange in fair value of convertible debentures embedded derivative liabilitiesChange in fair value of convertible debentures embedded derivative liabilitiesChange In Fair Value Of Convertible Debentures Embedded Derivative LiabilitiesChange in fair value of convertible debentures embedded derivative liabilities.Entity Common Stock, Shares OutstandingConvertible debenturesConvertible DebenturesDeferred Tax Liabilities Convertible DebentureAmount of deferred tax liability attributable to taxable temporary differences from Convertible Debentures.Expenses related to the annual maintenance feeAnnual Maintenance Fee Under License AgreementAnnual maintenance fee under license agreementAccrued expenses and other liabilitiesIncrease (Decrease) in Accrued Liabilities and Other Operating LiabilitiesWarrants issued during period, valueWarrants Issued During Period, ValueWarrants issued during period, value.Entity Listings [Table]Basis of Accounting, Policy [Policy Text Block]Basis of PresentationTitle and Position [Domain]Domestic (Canada)Income (Loss) from Continuing Operations before Income Taxes, DomesticWarrant value issued as part of amended term loan.Warrant Value Issued as Part of Amended Term LoanWarrant value issued as part of Amended Term LoanTransaction costsBusiness Acquisition, Transaction CostsCommon Stock, Value, IssuedCommon shares, no par value; unlimited shares authorized, 50,976,676 and 23,197,976 shares issued and outstanding as of October 31, 2024 and 2023, respectively.Warrants to purchase shares of common stockWarrants To Purchase Shares Of Common StockWarrants to purchase shares of common stock.Deemed dividend attributable to redeemable convertible preferred shareholdersDilutive Securities, Effect on Basic Earnings Per Share, ESOP Convertible Preferred StockDeemed dividend attributable to redeemable convertible preferred shareholdersInterest incomeInterest incomeInvestment Income, InterestSummary of Significant Accounting Policies [Table]Summary of significant accounting policies.Loan amortization dateLoan Amortization

~~***DateLoan amortization date.Cash and Cash Equivalents, Fair Value DisclosureCash equivalentsSchedule of Fair Value Hierarchy for Financial Assets Measured at Fair ValueFair Value, Assets Measured on Recurring Basis [Table Text Block]Other (income) expense, net:Other Nonoperating Income (Expense) [Abstract]Summary of Significant Accounting Policies [Line Items]Summary of significant accounting policies.Hercules CapitalHercules Capital [Member]Hercules capital.Long-Term Debt, Maturity, Year Three2027Acquirer.Acquirer [Domain]Operating lease liabilitiesOperating Lease, LiabilityTotal lease liabilityFair value of common shares and exercise price of options, MinimumShare Based Compensation Arrangement By Share Based Payment Award Fair Value of Common Shares and Exercise Price of Options MinimumShare based compensation arrangement by share based payment award fair value of common shares and exercise price of options minimum.Investment tax credits expiration yearInvestment Tax Credits Expiration YearInvestment tax credits expiration year.Measurement Frequency [Axis]Summary of Accrued Expenses and Other Current LiabilitiesSchedule of Accrued Liabilities [Table Text Block]Net operating loss (NOL) carryforwardsDeferred Tax Assets, Operating Loss CarryforwardsDeferred Tax Assets, Operating Loss Carryforwards, TotalIncremental compensation costShare-Based Payment Arrangement, Plan Modification, Incremental CostMarketable Securities [Line Items]Conversion and Exchange of Temporary Equity Into Common Shares in Connection With Reverse Recapitalization SharesConversion and exchange of redeemable convertible preferred shares into common shares in connection with the Reverse Recapitalization (in shares)Conversion and exchange of temporary equity into common shares in connection with reverse recapitalization shares.Loan and Security AgreementLoan and Security Agreements [Member]Loan and security agreements.Convertible notes and warrants issuedConvertible Notes And Warrants IssuedConvertible notes and warrants issued.Weighted-average number of common shares used in net loss per share, dilutedWeighted Average Number of Shares Outstanding, Diluted, TotalWeighted Average Number of Shares Outstanding, DilutedWeighted-average common shares outstanding, dilutedSignificant Accounting Policies [Text Block]Summary of Significant Accounting PoliciesConvertible debenturesConvertible Debt, NoncurrentRedeemable convertible preferred sharesRedeemable Convertible Preferred Stock [Member]Operating lease renewal termLessee, Operating Lease, Renewal TermRemaining options vestingShares VestingShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and Expected to Vest, Outstanding, NumberAdditional lease commitments to be paidLessee, Operating Lease, Liability, to be PaidTotalAdvance on loan allocated to warrants.Advance on Loan Allocated to Warrants.Advance on loan allocated to warrantsCybersecurity Risk Management Third Party Engaged [Flag]Less transaction costs previously deferred and netted against proceedsTransactions costs deferred and netted against proceedsTransactions Costs Deferred and Netted Against ProceedsTransactions costs deferred and netted against proceeds.Denominator:Weighted Average Number of Shares Outstanding, Diluted [Abstract]Warrants, maturity dateWarrants and Rights Outstanding, Maturity DatePercentage of total commitment amountPercentage Of Commitment AmountPercentage of commitment amount.2021 Loan and Security Agreement2021 Loan and Security Agreement [Member]2021 loan and security agreement.Non-cash interest expenseNon-cash Interest ExpenseNon-cash interest expense.Entity Small BusinessCybersecurity Risk Management Processes for Assessing, Identifying, and Managing Threats [Text Block]Debt instrument, basis spread on variable rateTerm loan annual interest rateDebt Instrument, Basis Spread on Variable RateWarrant termWarrant TermWarrant term.Notes PayableDebt Disclosure [Text Block]Change in fair value of convertible debenturesChange In Fair Value Of Convertible DebenturesChange in fair value of convertible debentures.Net operating loss carryforwards expiration yearNet Operating Loss Carryforwards Expiration YearNet Operating Loss Carryforwards Expiration YearIssuance Of Common Shares In Connection With Pipe Financing SharesIssuance of common shares in connection with pipe financing shares.Issuance of common shares in connection with PIPE Financing, net of issuance costs (in shares)Share exchange ratioStockholders' Equity Note, Stock Split, Conversion RatioU.S. Government TreasuriesUS Treasury Securities [Member]US TreasuryInvestments, Fair Value Disclosure, TotalInvestments, Fair Value DisclosureMarketable securitiesNew Laboratory and Office SpaceNew Laboratory and Office Space [Member]New laboratory and office space.Credit Facility [Axis]Percentage of price paid per share in non qualified financingPercentage Of Price Paid Per Share In Non Qualified FinancingPercentage of price paid per share in non qualified financing.Interest free periodDebt Instrument Interest Free PeriodDebt instrument interest free period.Initial maturity periodDebt Instrument Initial Maturity PeriodDebt instrument initial maturity period.Series 2 Class C Redeemable Convertible PreferredSeries 2 Class C Redeemable Convertible Preferred [Member]Series 2 class c redeemable convertible preferred.Redeemable Preferred Stock DividendsDeemed dividend attributable to redeemable convertible preferred shareholdersSection 174 capitalized R&D costsCapitalized Research And DevelopmentCapitalized research and developmentAmortization of (premium) discount on marketable securities.Amortization Of (Premium) Discount On Marketable SecuritiesAmortization of premium/discount on marketable securitiesCash flows from financing activitiesNet Cash Provided by (Used in) Financing Activities [Abstract]Exercise priceWeighted-Average Exercise Price Outstanding, Ending balanceWeighted-Average Exercise Price Outstanding, Beginning balanceShare-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Weighted Average Exercise PriceASU-2019-12Accounting Standards Update 2019-12 [Member]Term loan facility, drawn termLine of Credit Facility, Drawn TermLine of credit facility, drawn term.Amortization of debt discountAmortization of Debt Discount (Premium)Amortization of premium/discount on marketable securitiesUpfront feeUpfront FeesUpfront FeesFair value of convertible debenture embedded derivative liabilities recognized upon issuanceFair Value, Net Derivative Asset (Liability) Measured on Recurring Basis, Unobservable Inputs Reconciliation, IssuesPatent CostsPatent Costs Policy [Policy Text Block]Patent costs.Issuance of common shares upon cashless exercise of options (in shares)Stock Issued During Period Shares Upon Cashless Exercise of OptionsStock issued during period shares upon cashless exercise of options.Asset Class [Axis]Less transaction costs withheld from cash proceeds on Closing DateTransaction costs withheld from proceeds receivedTransaction Costs Withheld From Proceeds ReceivedTransaction costs withheld from proceeds received.Percentage of aggregate principle amount of term loan advances amount fee.Percentage of aggregate principle amount of term loan advances amount feePercentage of Aggregate Pricipal Amount of Term Loan Advances Amount FeeU.SState and Local Jurisdiction [Member]Right-of-Use Asset Obtained in Exchange for Operating Lease LiabilityRight of use assets obtained in exchange for lease liabilitiesCommon share options issuedCommon Share Options IssuedCommon Share Options IssuedMeasurement Frequency [Domain]Preferred shares fair valuePreferred Shares Fair ValuePreferred shares fair value.Reverse recapitalization shares converted on exchange of common shareReverse Recapitalization Shares Converted on Exchange of Common ShareReverse recapitalization shares converted on exchange of common share.Private Placement Warrants [Member]Private Placement Warrants [Member]Private placement warrants.Valuation allowanceValuation allowanceDeferred Tax Assets, Valuation AllowanceTemporary Equity, Shares OutstandingEnding balance (in shares)Beginning balance (in shares)Temporary equity shares outstandingOther Comprehensive Income (Loss), Net of Tax, Portion Attributable to Parent, TotalOther Comprehensive Income (Loss), Net of Tax, Portion Attributable to ParentOther comprehensive lossLevel 3Fair Value, Inputs, Level 3 [Member]Subsequent Events [Text Block]Subsequent EventsCybersecurity Risk Management Positions or Committees Responsible [Flag]Accounts payableAccounts Payable, CurrentAccounts Payable, Current, TotalChange in Accounting Principle, Accounting Standards Update, Immaterial EffectChange in Accounting Principle, Accounting Standards Update, Immaterial Effect [true false]Short-term operating lease costShort-Term Lease, Cost XML 27 R1.htm IDEA: XBRL DOCUMENT***~~

Document and Entity Information - USD ($)	**12 Months Ended**		
	Oct. 31, 2024	**Dec. 16, 2024**	**Apr. 30, 2024**
Entity Listings [Line Items]			
Document Type	10-K		
Amendment Flag	false		
Document Annual Report	true		
Document Transition Report	false		
Document Period End Date	Oct. 31, 2024		
Document Fiscal Year Focus	2024		
Entity File Number	001-41854		
Entity Registrant Name	enGene Holdings Inc.		
Entity Well-known Seasoned Issuer	No		
Entity Voluntary Filers	No		
Entity Current Reporting Status	Yes		
Entity Interactive Data Current	Yes		
ICFR Auditor Attestation Flag	false		
Entity Filer Category	Non-accelerated Filer		
Current Fiscal Year End Date	--10-31		
Document Fiscal Period Focus	FY		
Entity Incorporation, State or Country Code	A1		
Entity Central Index Key	0001980845		
Entity Tax Identification Number	00-0000000		
Document Financial Statement Error Correction [Flag]	false		
Entity Small Business	true		
Entity Emerging Growth Company	true		
Entity Shell Company	false		
Entity Address, Address Line One	4868 Rue Levy, Suite 220		
Entity Address, City or Town	Saint-Laurent		
Entity Address, State or Province	QC		
Entity Address, Country	CA		
Entity Address, Postal Zip Code	H4R 2P1		
City Area Code	514		

Local Phone Number	332-4888		
Entity Ex Transition Period	true		
Entity Public Float			$ 533,605,876
Entity Common Stock, Shares Outstanding		50,976,676	
Documents Incorporated by Reference	**DOCUMENTS INCORPORATED BY REFERENCE** Portions of the definitive proxy statement of enGene Holdings Inc. to be filed for its 2025 annual meeting of shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.		
Auditor Opinion	*Opinion on the Consolidated Financial Statements* We have audited the accompanying consolidated balance sheets of enGene Holdings Inc. (the “Company”) as of October 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred shares and shareholders’ equity (deficit), and cash flows for the years then ended, and the related notes (collectively, the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of October 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.		
Auditor Name	KPMG LLP		
Auditor Location	Montreal, Canada		
Auditor Firm ID	85		
Common Shares			
Entity Listings [Line Items]			
Trading Symbol	ENGN		
Title of 12(b) Security	Common Shares		
Security Exchange Name	NASDAQ		
Warrants, each exercisable for one Common share, at an exercise price of $11.50 per share			
Entity Listings [Line Items]			
Trading Symbol	ENGNW		
Title of 12(b) Security	Warrants, each exercisable for one Common Share, at an exercise price of $11.50 per share		
Security Exchange Name	NASDAQ		

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CONSOLIDATED BALANCE SHEETS - USD ($) $ in Thousands	**Oct. 31, 2024**	**Oct. 31, 2023**
Current assets:		
Cash and cash equivalents	$ 173,004	$ 81,521
Marketable securities - short term	65,328	
Restricted investments	72	76
Investment tax credits receivable	332	2,343
Prepaid and other current assets	8,626	1,500
Total current assets	247,362	85,440
Marketable securities - long term	59,527	
Property and equipment, net	1,169	589
Operating lease right of use assets	1,741	
Other assets	1,374	930
Total assets	311,173	86,959
Current liabilities:		
Accounts payable	1,411	1,156
Accrued expenses and other current liabilities	12,128	3,539
Operating lease liabilities, current	423	
Current portion of note payable	699	562
Total current liabilities	14,661	5,257
Note payable, net of current portion	22,473	9,216
Operating lease liabilities, net of current portion	1,427	
Liabilities, Total	38,561	14,473
Shareholders' equity:		
Common shares, no par value; unlimited shares authorized, 50,976,676 and 23,197,976 shares issued and outstanding as of October 31, 2024 and 2023, respectively.	509,811	259,373
Additional paid-in capital	18,950	13,717
Accumulated other comprehensive loss	(1,419)	(1,016)
Accumulated deficit	(254,730)	(199,588)
Total shareholder's equity	272,612	72,486
Total liabilities and shareholder's equity	$ 311,173	$ 86,959

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CONSOLIDATED BALANCE SHEETS (Parenthetical) - $ / shares	**12 Months Ended**	
	Oct. 31, 2024	**Oct. 31, 2023**
Common stock no par value		
Common stock shares authorized unlimited	Unlimited	Unlimited
Common stock shares issued	50,976,676	23,197,976
Common stock shares outstanding	50,976,676	23,197,976

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CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS - USD ($) $ in Thousands	**12 Months Ended**	
	Oct. 31, 2024	**Oct. 31, 2023**
Operating expenses:		
Research and development	$ 38,315	$ 16,458
General and administrative	23,982	9,602
Total operating expenses	62,297	26,060
Loss from operations	62,297	26,060
Other (income) expense, net:		
Change in fair value of convertible debentures embedded derivative liabilities		21,421
Change in fair value of warrant liabilities		(10,849)
Change in fair value of convertible debentures		56,212
Interest income	(10,413)	(1,117)
Interest expense	2,798	4,953
Loss on extinguishment of convertible debentures		3,091
Gain on extinguishment of debt	366	
Other expense, net	113	129
Total other (income) expense, net	(7,136)	73,840

Net loss before income taxes	55,161	99,900
Provision for (recovery of) income taxes	(19)	17
Net loss	55,142	99,917
Deemed dividend attributable to redeemable convertible preferred shareholders		4,822
Net loss attributable to common shareholders, basic	55,142	104,739
Net loss attributable to common shareholders, diluted	55,142	104,739
Other comprehensive loss:		
Unrealized loss on available-for-sale investments	(403)	
Total comprehensive loss	$ 54,739	$ 99,917
Net loss per share of common shares, basic	$ 1.46	$ 151.22
Net loss per share of common shares, diluted	$ 1.46	$ 151.22
Weighted-average common shares outstanding, basic	37,782,346	692,609
Weighted-average common shares outstanding, diluted	37,782,346	692,609

~~*XML 31 R5.htm IDEA: XBRL DOCUMENT*~~

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT) - USD ($)	Total	February PIPE Financing	October PIPE Financing	Common Shares	Common Shares February PIPE Financing	Common Shares October PIPE Financing	Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Class A Redeemable Convertible Preferred Shares	Class B Redeemable Convertible Preferred Shares	Class C Redeemable Convertible Preferred Shares
Beginning balance (in shares) at Oct. 31, 2022										266,696	156,036	5,560,607
Beginning balance at Oct. 31, 2022										$ 1,899,000	$ 1,554,000	$ 49,665,000
Beginning balance (in shares) at Oct. 31, 2022				665,767								
Beginning balance at Oct. 31, 2022	$ (76,614,000)			$ 16,390,000			$ 7,683,000	$ (1,016,000)	$ (99,671,000)			
Exercise of stock options (in shares)				47,186								
Exercise of stock options	44,000			$ 79,000			(35,000)					
Issuance of common shares upon cashless exercise of options (in shares)				15,494								
Issuance of common shares upon cashless exercise of options				$ 11,000			(11,000)					
Conversion and exchange of Old enGene convertible debentures and common share warrants into enGene Holdings common shares and common share warrants in connection with the Reverse Recapitalization (in shares)				6,379,822								
Conversion and exchange of Old enGene convertible debentures and common share warrants into enGene Holdings common shares and common share warrants in connection with the Reverse Recapitalization	140,393,000			$ 138,410,000			1,983,000					
Conversion and exchange of redeemable convertible preferred shares into common shares in connection with the Reverse Recapitalization (in shares)										(266,696)	(156,036)	(5,560,607)
Conversion and exchange of redeemable convertible preferred shares into common shares in connection with the Reverse Recapitalization										$ (1,899,000)	$ (1,554,000)	$ (49,665,000)
Conversion and exchange of redeemable convertible preferred stock into common shares in connection with the Reverse Recapitalization (in shares)				5,983,339								
Conversion and exchange of redeemable convertible preferred stock into common shares in connection with the Reverse Recapitalization	53,118,000			$ 53,118,000								
Common shares and common share warrants issued upon Reverse Recapitalization and PIPE Financing, net of issuance costs of $11.1 million (in shares)				10,106,368								
Common shares and common share warrants issued upon Reverse Recapitalization and PIPE Financing, net of issuance costs of $11.1 million	52,012,000			$ 51,365,000			647,000					
Share-based compensation expense	3,450,000						3,450,000					
Net Income (Loss)	(99,917,000)								(99,917,000)			
Ending balance (in shares) at Oct. 31, 2023				23,197,976								
Ending balance at Oct. 31, 2023	$ 72,486,000			$ 259,373,000			13,717,000	(1,016,000)	(199,588,000)			
Exercise of stock options (in shares)	116,752			116,752								
Exercise of stock options	$ 113,000			$ 295,000			(182,000)					
Issuance of common shares in connection with PIPE Financing, net of issuance costs (in shares)					20,000,000	6,758,311						
Issuance of common shares in connection with PIPE Financing, net of issuance costs		$ 187,614,000	$ 56,318,000		$ 187,614,000	$ 56,318,000						
Issuance of warrants in connection with Amended Term Loan	319,000						319,000					
Issuance of common shares												

upon exercise of warrants (in shares)		520,282			
Issuance of common shares upon exercise of warrants	5,983,000	$ 6,114,000	(131,000)		
Issuance of common shares upon cashless exercise of warrants (in shares)		383,355			
Issuance of common shares upon cashless exercise of warrants		$ 97,000	(97,000)		
Share-based compensation expense	5,324,000		5,324,000		
Other comprehensive loss	(403,000)			(403,000)	
Net Income (Loss)	(55,142,000)				(55,142,000)
Ending balance (in shares) at Oct. 31, 2024		50,976,676			
Ending balance at Oct. 31, 2024	$ 272,612,000	$ 509,811,000	$ 18,950,000	$ (1,419,000)	$ (254,730,000)

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CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT) (Parenthetical) $ in Millions	12 Months Ended
	Oct. 31, 2023 USD ($)
Issuance costs	$ 11.1

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CONSOLIDATED STATEMENT OF CASH FLOWS - USD ($) $ in Thousands	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Cash Flows from operating activities:		
Net loss	$ (55,142)	$ (99,917)
Adjustments to reconcile net loss to net cash used in operating activities		
Non-cash interest expense	806	778
Loss on extinguishment of convertible debentures		3,091
Gain on extinguishment of debt	366	
Change in fair value of warrant liabilities		(10,849)
Change in fair value of convertible debenture embedded derivative liabilities		21,421
Change in fair value of convertible debentures		56,212
Loss on the disposal of property and equipment	22	
Debt issuance costs expensed upon issuance of convertible debentures recorded using the fair value option		924
Non-cash lease expense	163	
Amortization of premium/discount on marketable securities	(232)	
Unrealized foreign currency (gain) losses	(6)	489
Share-based compensation expense	5,324	3,450
Depreciation of property and equipment	323	175
Changes in operating assets and liabilities:		
Investment tax credit receivable	2,011	(1,007)
Prepaid expenses and other assets	(7,566)	(751)
Accounts payable	474	373
Accrued expenses and other liabilities	5,225	868
Lease liabilities	(49)	
Net cash used in operating activities	(48,281)	(24,743)
Cash flows from investing activities		
Purchases of property and equipment	(925)	(318)
Purchases of investments	(125,028)	
Net cash used in investing activities	(125,953)	(318)
Cash flows from financing activities		
Proceeds from PIPE financings	260,149	56,892
Payments of issuance costs associated with the 2024 PIPE Financings	(12,386)	
Proceeds from FEAC trust account in connection with Reverse Recapitalization		7,363
Payment of Reverse Recapitalization and PIPE Financing costs	(613)	(10,497)
Proceeds from issuance of April 2023 Notes		38,000
Payment of issuance costs associated with April 2023 Notes		(924)
Repayment of convertible debentures		(3,176)
Proceeds from exercise of stock options	113	44
Proceeds from exercise of common share warrants	5,983	
Repayments of term loan principal	(9,445)	(1,555)
Proceeds from issuance of term loan	22,500	
Payments of debt issuance costs associated with the term loan	(585)	
Net cash provided by financing activities	265,716	86,147
Effect of exchange rate changes on cash	1	1
Net increase in cash and cash equivalents	91,483	61,087
Cash and cash equivalents at beginning of period	81,521	20,434
Cash and cash equivalents at end of period	173,004	81,521
Supplemental cash flow information:		
Cash paid for interest	1,925	1,398
Supplemental disclosure of non-cash investing and financing activities		
Reverse Recapitalization and PIPE financing transaction costs included within accrued expenses	3,831	613
Conversion of Preferred Shares upon Reverse Recapitalization		53,118
Warrant value issued as part of Amended Term Loan	319	
Conversion of Convertible Debentures upon Reverse Recapitalization		113,627
Reclassification of warrant liability to equity upon Reverse Recapitalization		1,983
Liabilities assumed upon Reverse Recapitalization		1,130
Warrant liability recognized upon issuance of term loan		1,420
Settlement of derivative liability upon repayment and conversion of convertible debentures		25,217
Right of use assets obtained in exchange for lease liabilities	$ 1,904	
Fixed assets included in accrued expenses and accounts payable		58
Settlement of April 2023 Notes through the issuance of May 2023 Notes and warrants		$ 8,000

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Pay vs Performance Disclosure - USD ($) $ in Thousands	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Pay vs Performance Disclosure		
Net Income (Loss)	$ (55,142)	$ (99,917)

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Insider Trading Arrangements	3 Months Ended Oct. 31, 2024
Trading Arrangements, by Individual	
Rule 10b5-1 Arrangement Adopted	false
Non-Rule 10b5-1 Arrangement Adopted	false
Rule 10b5-1 Arrangement Terminated	false
Non-Rule 10b5-1 Arrangement Terminated	false

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Cybersecurity Risk Management, Strategy and Governance	12 Months Ended Oct. 31, 2024
Cybersecurity Risk Management, Strategy, and Governance [Line Items]	
Cybersecurity Risk Management Processes for Assessing, Identifying, and Managing Threats [Text Block]	**Item 1C. Cybersecurity.** **Cybersecurity Risk Management and Strategy** We have implemented cybersecurity risk management procedures, in accordance with our risk profile and business size, that are designed to identify, assess, and mitigate risks from current and emerging cybersecurity threats. Our cybersecurity procedures, which are informed by the National Institute of Standards and Technology cybersecurity framework, are supported by a third-party managed services provider that assists us in managing our IT systems. We maintain cyber insurance coverage; however, such insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks, and other related breaches. Our cybersecurity procedures are comprised of a variety of tools designed to protect our data and information technology systems, including but not limited to endpoint protection and network security measures, that are supported by our third-party service providers. We also have a process to require our employees to undergo cybersecurity awareness training. Further, we plan to implement a process to review risks to our Company in connection with certain third-party providers and vendors, which we expect will involve assessments through vendor questionnaires, as appropriate. To date, we have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party IT service providers and vendors have from time to time experienced threats that could affect our information or systems. For more information, see, “Risk Factors,” in this Annual Report. **Cybersecurity Governance** Our cybersecurity program is managed and directed by our Vice President, Information Technology, or IT, who has approximately 20 years of experience in information technology and information systems management. Our Vice President, IT reports to our Chief Financial Officer. One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight. Our Audit Committee is responsible for overseeing the Company’s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes cybersecurity risk. A cybersecurity update is provided at least annually, or more frequently as needed, to the Audit Committee by members of management responsible for managing cybersecurity risks.
Cybersecurity Risk Management Third Party Engaged [Flag]	true
Cybersecurity Risk Third Party Oversight and Identification Processes [Flag]	true
Cybersecurity Risk Materially Affected or Reasonably Likely to Materially Affect Registrant [Flag]	false
Cybersecurity Risk Board of Directors Oversight [Text Block]	Our cybersecurity program is managed and directed by our Vice President, Information Technology, or IT, who has approximately 20 years of experience in information technology and information systems management. Our Vice President, IT reports to our Chief Financial Officer. One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight. Our Audit Committee is responsible for overseeing the Company’s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes cybersecurity risk. A cybersecurity update is provided at least annually, or more frequently as needed, to the Audit Committee by members of management responsible for managing cybersecurity risks.
Cybersecurity Risk Board Committee or Subcommittee Responsible for Oversight [Text Block]	Our Audit Committee is responsible for overseeing the Company’s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes cybersecurity risk.
Cybersecurity Risk Process for Informing Board Committee or Subcommittee Responsible for Oversight [Text Block]	A cybersecurity update is provided at least annually, or more frequently as needed, to the Audit Committee by members of management responsible for managing cybersecurity risks.
Cybersecurity Risk Role of Management [Text Block]	One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight.
Cybersecurity Risk Management Positions or Committees Responsible [Flag]	true
Cybersecurity Risk Management Positions or Committees Responsible [Text Block]	Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight. Our Audit Committee is responsible for overseeing the Company’s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes cybersecurity risk.
Cybersecurity Risk Management Expertise of Management Responsible [Text Block]	Our cybersecurity program is managed and directed by our Vice President, Information Technology, or IT, who has approximately 20 years of experience in information technology and information systems management.
Cybersecurity Risk Process for Informing Management or Committees Responsible [Text Block]	One of the key functions of our Board of Directors is informed oversight of our risk management process.
Cybersecurity Risk Management Positions or Committees Responsible Report to Board [Flag]	true

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Description of Business	12 Months Ended Oct. 31, 2024
Organization, Consolidation and Presentation of Financial Statements [Abstract]	
Description of Business	**1. Description of Business** enGene Holdings Inc. (together with its consolidated subsidiaries “enGene” or the “Company”) formed in connection with the Merger Agreement (as defined below) was incorporated as 14963148 Canada Inc. under the federal laws of Canada on April 24, 2023 and changed its name to enGene Holdings Inc. on May 9, 2023. On October 31, 2023, enGene Holdings Inc. continued from being a corporation incorporated under and governed by the Canada Business Corporations Act to a company continued to and governed by the Business Corporations Act (British Columbia). The Company is a clinical-stage biotechnology company focused on developing genetic medicines to improve the lives of patients, and its head office is located in Montreal, Quebec, Canada. The Company is developing non-viral genetic medicines based on its novel and proprietary dually derived chitosan, or “DDX”, gene delivery platform, which allows localized delivery of multiple gene cargos directly to mucosal tissues and other organs. ***Merger with Forbion European Acquisition Corp.*** Forbion European Acquisition Corporation (“FEAC”) was a special purpose acquisition company (“SPAC”), incorporated as a Cayman Island exempted company on August 9, 2021 and formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more business or entities. On October 31, 2023 (the “Closing Date”), the Company, FEAC, and enGene Inc., consummated the merger (the “Reverse Recapitalization”) pursuant to a business combination agreement, dated as of May 16, 2023 (the “Merger Agreement”). The transaction was accounted for as a “reverse recapitalization” in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). Under this method of accounting,

FEAC was treated as the "acquired" company for financial reporting purposes. This determination is primarily based on the fact that subsequent to the Reverse Recapitalization, senior management of Old enGene continued as senior management of the combined company; Old enGene identified a majority of the members of the board of directors of the combined company; the name of the combined company is enGene Holdings Inc. and it utilized Old enGene's current headquarters, and Old enGene's operations comprise the ongoing operations of the combined company. Accordingly, for accounting purposes, the Company is considered to be a continuation of Old enGene, with the net identifiable assets of FEAC deemed to have been acquired by Old enGene in exchange for Old enGene common shares accompanied by a recapitalization, with no goodwill or intangible assets recorded. The number of redeemable convertible preferred shares, number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization, have been retrospectively restated to reflect an exchange ratio of approximately 0.18048 (the "Exchange Ratio") established in the Merger Agreement. Operations prior to the Reverse Recapitalization are those of Old enGene.

As a result of the Reverse Recapitalization, the Company became a publicly traded company, and listed its Common Shares and warrants on the Nasdaq Global Market under the symbols "ENGN" and "ENGNW," respectively, commencing trading on November 1, 2023, with Old enGene, a subsidiary of the Company, continuing the existing business operations.

Liquidity and Going Concern

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern,* the Company has evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date these consolidated financial statements are issued.

The Company's consolidated financial statements have been prepared assuming the Company will continue as a going concern, which presumes the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the ordinary course of business.

As an emerging growth entity, the Company has devoted substantially all of its resources since inception to organizing and staffing the Company, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, research and development activities for developing non-viral genetic medicines and other compounds, establishing arrangements with third parties for the manufacture of its product candidates and component materials, and providing general and administrative support for these operations. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future. The Company has not yet commercialized any product candidates and does not expect to generate revenue from sales of any product candidates or from other sources for several

years, if at all. The Company will need substantial additional funding to support its continuing operations and pursue its development strategy.

The Company has incurred a net loss of $55.1 million and negative cash flows from operating activities of $48.3 million for year ended October 31, 2024, and, as of that date, has an accumulated deficit of $254.7 million. To date, the Company has not generated any revenues and has financed its liquidity needs primarily through the 2024 PIPE Financings, the Reverse Recapitalization and the PIPE financing conducted by the Company as part of the Reverse Recapitalization (the "PIPE Financing"), debt and convertible debentures, and issuance of redeemable convertible preferred shares and warrants.

The Company's ability to continue as a going concern depends on its ability to successfully develop and commercialize its products, achieve and maintain profitable operations, as well as the adherence to conditions of outstanding loans. As of the issuance date of these consolidated financial statements, the Company expects that its existing cash and cash equivalents as of October 31, 2024 will be sufficient to fund its operating expenses and debt obligations requirements for at least the next 12 months from the issuance date of these consolidated financial statements. Effective from the Company's first quarter interim condensed consolidated financial statements, the Company has ceased its disclosure of the existence of a material uncertainty that raised substantial doubt about the Company's ability to continue as a going concern due to the February 2024 PIPE Financing.

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Summary of Significant Accounting Policies	**12 Months Ended** **Oct. 31, 2024**
Accounting Policies [Abstract]	
Summary of Significant Accounting Policies	

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are prepared in accordance with U.S. GAAP and include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Updates ("ASU's") of the Financial Accounting Standards Board ("FASB").

The consolidated financial statements are expressed in US dollars. The consolidated financial statements have been prepared on a historical cost basis, except for items that are required to be accounted for at fair value.

As the merger with FEAC has been accounted for as a reverse recapitalization, the historical operations of the Company represent that of Old enGene which is the accounting predecessor. The number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization have been retrospectively restated to reflect the Exchange Ratio of approximately 0.18048 established in the Merger Agreement. Please see Note 3, Reverse Recapitalization for additional information.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include but are not limited to the accrual of research and development expenses, share-based payments and the recoverability of investment tax credits receivable and, in addition, for fiscal 2023: the valuations of common shares, redeemable convertible preferred shares, warrants to purchase redeemable convertible preferred shares, convertible debentures, and embedded derivatives on convertible debt. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Actual results could differ from those estimates and such differences may be material to the consolidated financial statements.

Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates as a single business segment focused on research, discovery, and clinical development of human genetic medicine products. The majority of the Company's tangible assets are held in Canada.

Risk of Concentrations of Credit and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits. Management believes that the Company is not currently exposed to significant credit risk as the Company's deposits were held in custody at third-party financial institutions.

The Company's investment policy limits investments to certain types of securities issued by the U.S. Government and its agencies, as well as institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of marketable securities to the extent recorded on the Consolidated Balance Sheets. As of October 31, 2024 and 2023, the Company had no off-balance sheet concentrations of credit risk.

The Company is dependent on third-party CDMOs and CRO with whom it does business. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities in its programs. The Company also relies on a limited number of third-party CROs to perform research and development activities on its behalf. These programs could be adversely affected by significant interruption from these providers.

Cash and Cash Equivalents

The Company considers all short-term, highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company's cash and cash equivalents include bank balances, demand deposits and other short-term, highly liquid investments. The fair value of cash and cash equivalents approximate the amortized cost. The Company had $173.0 million of cash and cash equivalents as of October 31, 2024 and $81.5 million of cash as of October 31, 2023.

Marketable securities

The Company's marketable securities are maintained by investment managers and consist of money market funds, U.S. government agency securities and treasuries. If the remaining contractual maturity is within one year from the balance sheet date, the marketable securities are classified as current and otherwise, they are classified as non-current assets.

Investment in marketable securities is classified as available-for-sale and is reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale securities are reported as a separate component of stockholders' equity in other comprehensive loss. Premium or discounts from par value are amortized to investment income over the life of the underlying investment.

The Company periodically evaluates the need for an allowance for credit losses. The evaluation includes consideration of several qualitative and quantitative factors, including whether it has plans to sell the security, whether it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis, and if the entity has the ability and intent to hold the security to maturity, and the portion of any unrealized loss that is the result of a credit loss. Factors considered in making these evaluations include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, expected cash flows from securities, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and the Company's strategy and intentions for holding the marketable security.

When the fair value is below the amortized cost of the asset, an estimate of expected credit losses is made. The Company records credit losses in the consolidated statements of operations and comprehensive loss as a credit loss expense within other income, net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale securities.

Accrued interest receivable related to the Company's available-for-sale securities is presented within prepaids and other current assets on the Company's consolidated balance sheets. The Company has elected the practical expedient available to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivable associated with its marketable securities.

Property and Equipment

Property and equipment are comprised mainly of research and development equipment, computer hardware and software, office furniture and equipment, and leasehold improvements. Property and equipment are stated at cost less accumulated depreciation and accumulated impairment losses, if applicable. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Lab equipment	5 years
Computer equipment	3 years
Computer software	5 years
Office furniture	5 years
Leasehold improvements	Shorter of remaining lease term or useful life

Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheet and any resulting gains or losses are included in the consolidated statements of operations and comprehensive loss in the period of disposal.

The Company reviews long-lived assets, such as property and equipment, for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. If indicators of impairment are present, the assets are tested for recoverability by comparing the carrying amount of the assets to the related estimated future undiscounted cash flows that the assets are expected to generate. If the expected undiscounted cash flows are less than the carrying value of the assets, then the assets are considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows. To date, no such impairment losses have been recorded.

Leases

The Company adopted FASB ASC 842 with an effective date of November 1, 2019, using the modified retrospective transition approach which uses the effective date as the date of initial application. In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use ("ROU") asset and a lease liability on the consolidated balance sheet for all leases with an initial lease term of greater than 12 months. The Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.

Fair Value Measurements of Financial Instruments

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

At October 31, 2024, financial instruments measured at fair value on a recurring basis include marketable securities (see Note 5, Marketable Securities, and Note 4, Fair Value Measurements). The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term nature.

Fair Value Option

The Company elected the fair value option of accounting of ASC 825 for all convertible debentures issued in fiscal 2023 from their issuance date in order to not have to bifurcate any embedded derivatives in accordance with ASC 815. The notes for which the fair value option of accounting is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the notes accounted for at fair value, which include accrued interest, if any, are recorded as a component of other expense (income), net in the consolidated statement of operations and comprehensive loss. The Company has not elected to present interest expense separately from changes in fair value and therefore will not present interest expense associated with the notes. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income. During the year ended October 31, 2023, the Company did not record any changes in fair value related to instrument-specific credit risk. All costs associated with the issuance of the convertible debentures accounted for using the fair value option were expensed upon issuance.

Debt Issuance Costs

The Company capitalizes certain legal, accounting, and other third-party fees that are directly associated with the issuance of debt not accounted for using the fair value option as debt issuance costs. Debt issuance costs are recorded as a direct reduction of the carrying amount of the associated debt on the Company's consolidated balance sheets and amortized as interest expense on the Company's consolidated statements of operations and comprehensive loss using the effective interest method.

Convertible Debenture Embedded Derivative Liabilities

The Company's convertible debentures contained certain features that meet the definition of embedded derivatives requiring bifurcation from the convertible debenture instrument, for which the fair value option was not elected, as a separate compound derivative. The convertible debenture embedded derivative liabilities are initially measured at fair value on issuance and is subject to remeasurement at each reporting period with changes in fair value recognized in the change in fair value of derivative liabilities, net in the consolidated statements of operations and comprehensive loss.

Common Share and Preferred Share Warrants

The Company accounts for its common share warrants and redeemable convertible preferred shares warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants that have been determined to be classified as liabilities are recorded on the consolidated balance sheets at their fair value on the date of issuance and remeasured to fair value at each reporting period, with the changes in fair value recognized in the change in fair value of warrant liabilities, net in the consolidated statements of operations and comprehensive loss. The Company adjusted the liability for changes in the fair value of these warrants until the earlier of the exercise of the warrants, the expiration of the warrants, or until such time as the warrants were no longer considered liability.

Convertible Debentures

The Company's 2022 Notes (as defined in Note 9, Notes Payable) are convertible debentures that consist of a debt instrument, a minimum interest obligation, and a share conversion feature. Certain of the convertible debentures issued by the Company also included warrants to purchase redeemable convertible preferred shares, which were classified as liabilities. The Company identified embedded derivatives related to certain share conversion and repayment features within the convertible notes that required bifurcation as a single compound derivative instrument. At inception, the Company utilized the residual method to determine the value of the debt instrument based on the difference between gross proceeds and the estimated fair value of the embedded derivative and any warrants that were issued. The debt instrument is accounted for using the amortized cost method. The discounts on debt resulting from any issuance costs, embedded derivatives and warrants are amortized over the life of the debt using the effective interest method. The issuance costs allocated to the embedded derivatives and warrants are expensed at inception.

Research and Development Expenses

Research and development expenses are comprised primarily of costs incurred for our drug discovery efforts and development of our product candidates. These expenses include salaries, employee benefits, and share-based compensation expense for our research and development personnel, materials, supplies, depreciation on and maintenance of research equipment, the cost of services provided by outside CROs and consultants to conduct research and development activities including costs of clinical trials and manufacturing, and the allocable portions of facility costs, such as rent, utilities, and general support services. All costs associated with research and development are expensed as incurred.

Management estimates the Company's accrued research and development expenses as of each balance sheet date in the Company's financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent-related costs are classified as general and administrative expenses within the Company's consolidated statements of operations.

Share-Based Compensation

The Company has an incentive equity plan (the "2023 Incentive Equity Plan" or the "2023 Plan"), whereby employees render services as consideration for equity instruments. The 2023 Plan was adopted on October 31, 2023 upon the completion of the Reverse Recapitalization and superseded Old enGene's employee stock option plan (the "ESOP") and equity incentive plan (the "EIP") (collectively, the "Old Plans"). The Company measures all share-based awards granted to employees, officers, directors and non-employees based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures of its share-based awards as they occur. The Company issues share-based awards with service-based vesting conditions and awards with both performance and service-based vesting conditions. For share-based awards with service-based vesting conditions, the Company records the expense using the straight-line method including when such awards have graded vesting. For share-based awards with both performance and service-based vesting conditions, the Company records the expense using an accelerated attribution method, once the performance conditions are considered probable of being achieved, using management's best estimate.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the Company's common shares, expected share price volatility, the expected term of the award, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. The Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies with similar characteristics including market capitalization, stage of development, therapeutic focus and certain financial measures. The expected volatility has been determined using an average of the historical volatility measures of this group of guideline companies. The expected option term was calculated based on the simplified method for awards with only service based vesting conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to develop an estimate based on participant behavior. For awards with both performance and service based vesting conditions, the expected term has been determined using management's best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, if any, and comparison to expected terms used by peers. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common shares; therefore, the expected dividend yield is assumed to be zero.

Prior to the consummation of the Reverse Recapitalization, because there was no public market for the Company's common shares, the Board of Directors has determined the fair value of the Company's common shares based on third-party valuations of the Company's common shares. Initially, the estimated enterprise equity value of the Company was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Company's various securities of its capital structure using an option pricing method, or OPM, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another.

Significant assumptions used in the OPM to determine the fair value of common shares include volatility, discount for lack of marketability, and the expected timing of a future liquidity event such as an initial public offering ("IPO"), or sale of the Company in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios. In addition, the Company's Board of Directors considered various objective and subjective factors to determine the fair value of the Company's common shares as of each grant date, including the prices at which Old enGene sold shares of redeemable convertible preferred shares and the superior rights and preferences of the redeemable convertible preferred shares relative to its common shares at the time of each grant, external market conditions, the progress of the Company's research and development programs, the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results, and the lack of an active public market for the Company's common shares and redeemable convertible preferred shares, among other factors.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment and these valuations are sensitive to changes in the unobservable inputs. As a result, if the Company had used different assumptions or estimates or if there are changes to the unobservable inputs, the fair value of its common shares and share-based compensation expense could have been materially different.

Subsequent to becoming a publicly traded Company upon the consummation of the Reverse Recapitalization, the fair value of common shares underlying equity awards is based on the market price of the Company's common stock at the date of the grant.

The Company's share-based compensation expense is recorded in general and administrative and research and development expenses in the Company's consolidated statements of operations and comprehensive loss.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on differences between the consolidated financial statement carrying amounts and the tax basis of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in shareholders' deficit that result from transactions and economic events other than those with shareholders. The Company's comprehensive loss includes foreign currency translation.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common shares. Net loss per share attributable to common shareholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. Net loss attributable to common shareholders is allocated first based on dividend rights and then to common and preferred shareholders based on ownership interests on an as-converted basis as if all the earnings for the period had been distributed.

When considering the impact of the convertible equity instruments, diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred shareholders and warrant holders based on dividend rights and then to common and preferred shareholders and warrant holders based on ownership interests. As preferred shares have converted to common shares at the completion of Reverse Recapitalization, the abovementioned policy is only applicable for the year ended October 31, 2023. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, and the potential issuance of common shares upon the conversion of the convertible notes. Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders is generally the same as basic net loss per share attributable to common shareholders because dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. See Note 15, Net Loss per Share, for further detail.

Deferred Transaction Costs

The Company capitalized certain legal, professional accounting and other third-party fees that were directly associated with the Reverse Recapitalization and PIPE Financing as deferred transaction costs until such transaction was consummated. After the consummation of such transaction, these costs were recorded within equity as a reduction of the common share and warrant value within additional paid in capital, for both instruments issued and assumed to shareholders of FEAC and to PIPE financing investors, were allocated to each on a relative fair value basis. The Company incurred a total of $11.3 million of transaction costs as part of the Reverse Recapitalization and PIPE Financing. In addition, transaction costs of $0.8 million related to the issuance of the April 2023 Notes and the May 2023 Notes for which the fair value option of accounting was elected and those allocated to the liability classified warrants issued as part of the 2023 Financing are not deferred and are included in general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss.

Government Assistance Programs for Research and Development Expenditures

The Company was eligible to claim Canadian federal and provincial tax credits as a Canadian controlled private corporation ("CCPC") on eligible scientific research and experimental development ("SR&ED") expenditures through September 2023, at which time the Company lost its status as a CCPC. In addition, effective for fiscal 2023, the Company's maximum refundable tax credits were reduced due to the Company's taxable capital, as defined in the *Income Tax Act* (Canada), which reduction in credits has been recorded in the fourth quarter. The Canadian federal government offers a tax incentive to companies performing research and development activities in Canada and this tax incentive can be refunded or used to reduce federal income taxes in Canada otherwise payable. Such credits, if not refunded or used in the year earned, can be carried forward for a period of twenty years. The Quebec provincial government offers a similar refundable incentive. The investment tax credits recorded are based on management's estimates of amounts expected to be recovered and are subject to audit by the taxation authorities, the resulting adjustments of which could be significant. Following the loss of CCPC status, the Company's SR&ED tax credits will be earned at a lower rate and some will no longer be refundable.

Amounts received or receivable resulting from government assistance programs, including investment tax credits for SR&ED, are recognized when there is reasonable assurance that the amount will be received, and all attached conditions will be complied with. Reimbursements of eligible SR&ED expenditures pursuant to government assistance programs are received in cash. The amounts receivable are recorded as reductions of research and development costs when the related costs have been incurred and there is reasonable assurance regarding collection of the claim. During the years ended October 31, 2024 and 2023, the Company recorded $0.4 million and $1.1 million, respectively, as a reduction of research and development expense associated with SR&ED investment tax credits.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). This new standard changes the impairment model for most financial assets and certain other instruments. Entities will be required to use a model that will result in the earlier recognition of allowances for losses for trade and other receivables, held-to-maturity debt securities, loans, and other instruments. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. In November 2019, the FASB issued ASU 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) ("ASC 2019-10"), which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, for entities meeting the definition of a smaller reporting company. The Company adopted ASU 2016-13 effective November 1, 2023 and the adoption did not have a material impact on the consolidated financial statements.

Recently Issued Accounting Pronouncements – Not Yet Adopted

In June 2022, the FASB issued ASU No. 2022-03, Fair Value Measurement (Topic 820) – Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions, which amends guidance in ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company does not expect that the adoption of this standard will have a material impact on its financial statements and related disclosures.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which requires incremental disclosure of segment information on an interim and annual basis. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application to all prior periods presented in the financial statements is required for public entities. The Company is currently evaluating the impact of the guidance on the financial statements disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires entities to disclose additional information about specific expense categories in the notes to the financial statements. The ASU is effective for annual periods beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the effect of this update on its consolidated financial statements and related disclosures.

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Reverse Recapitalization	**12 Months Ended Oct. 31, 2024**
Stockholders' Equity Note [Abstract]	
Reverse Recapitalization	

3. Reverse Recapitalization

On October 31, 2023 (the "Closing Date"), FEAC, Old enGene, and the Company consummated the merger pursuant to the Merger Agreement, dated as of May 16, 2023. As a result of the Reverse Recapitalization, the Company became a publicly traded company, with old enGene, a subsidiary of the Company, continuing the existing business operations.

At the effective time of the Reverse Recapitalization:

- each outstanding share of Old enGene common stock was exchanged for the Company's common shares at the Exchange Ratio;
- each share of Old enGene's redeemable convertible preferred shares outstanding immediately prior to the close of the Reverse Recapitalization was exchanged for shares of the Company's common shares based on the same Exchange Ratio, with no dividends or distributions being declared or paid on Old enGene's redeemable convertible preferred shares;
- the 2022 Notes and May 2023 Notes (each as defined in Note 9, Notes Payable) of Old enGene's existing convertible notes outstanding immediately prior to the close of the Reverse Recapitalization were converted to Old enGene common shares at the conversion ratio in place at the time of conversion and were exchanged for shares of the Company at the Exchange Ratio; and
- each outstanding option to purchase Old enGene common stock became fully vested and converted into an option to purchase a number of the Company's common shares equal to the number of shares of old enGene common stock subject to such option multiplied by the Exchange Ratio, rounded down to the nearest whole share, at an exercise price per share equal to the current exercise price per share for such option divided by the Exchange Ratio, rounded up to the nearest whole cent;
- all of Old enGene's outstanding warrants exercisable for common shares in Old enGene were exchanged for warrants exercisable for the Company's common shares using the Exchange Ratio, with the warrants maintaining the same terms and conditions;
- all of Old enGene's existing outstanding Class C warrants outstanding at the time of the Reverse Recapitalization were terminated; and
- all outstanding FEAC Shares of 3,670,927 held by FEAC Sponsor and shareholders were converted into the same number of the Company's common shares, and outstanding FEAC warrants of 5,029,444 held by FEAC warrant holders were converted into the same number of warrants to purchase one share of the Company's common shares.

Upon the close of the Reverse Recapitalization, 13,091,608 common shares of the Company were issued to the Old enGene's equity and convertible note holders, 2,679,432 common share warrants of the Company were issued to Old enGene's warrant holders, and 2,706,941 common share options of the Company were issued to Old enGene's share option holders.

In connection with the Merger Agreement, FEAC, the Company, and PIPE Investors entered into Subscription Agreements pursuant to which, the PIPE Investors have agreed to purchase the Company's shares and warrants for an aggregate commitment amount of $56.9 million. As part of the PIPE Financing, the Company issued 6,435,441 shares of the Company's common shares and 2,702,791 warrants to purchase the Company's common shares for an aggregate purchase price equal to $56.9 million on October 31, 2023. The common shares and warrants issued as part of the PIPE Financing were determined to be equity classified. The proceeds were allocated between the common shares and warrants on a relative fair value basis, taking into consideration the quoted market price of the FEAC common shares and warrants on the close of the market on October 31, 2023, resulting in $56.1 million being allocated to the common shares and $0.8 million being allocated to the warrants. In connection with the Merger Agreement, FEAC, the FEAC Sponsor, Forbion Growth Opportunities Fund I Cooperatief U.A. and the other holders of FEAC Class B Shares, Old enGene, the Company and the other parties named therein entered into the Side Letter Agreements, pursuant to which the FEAC Sponsor agreed to surrender and in effect issue to PIPE Investors FEAC Class B shares and FEAC private placement warrants, immediately prior to the closing of the Reverse Recapitalization. Immediately following the Reverse Recapitalization and the PIPE Financing, the Company had 23,197,976 common shares and 10,411,641 warrants outstanding.

On October 31, 2023, as part of the close of Reverse Recapitalization, the Company received proceeds of $7.4 million, from the FEAC trust account, net of the redemption payment to FEAC's public shareholders and cash paid from the trust for FEAC expenses. Additionally, the Company received proceeds of approximately $56.9 million from the PIPE Financing. Upon the closing of the Reverse Recapitalization and PIPE Financing, the Company incurred $6.0 million in transaction costs, which was withheld from the proceeds received. The Company incurred a total of $11.1 million of transaction costs associated with the Reverse Recapitalization and PIPE Financing, of which $5.1 million was previously deferred by the Company and netted against the proceeds upon close. The transaction costs were allocated to the common shares and warrants on a relative fair value basis and netted against the proceeds upon close.

The following table summarizes the elements of the net proceeds from the Reverse Recapitalization and PIPE Financing transaction as of October 31, 2023:

	Recapitalization
Cash – FEAC's Trust Account and Cash (net of redemptions and cash paid for FEAC expenses prior to close)	$ 7,363
Cash – PIPE Financing	56,892
Less transaction costs withheld from cash proceeds on Closing Date	(6,024)
Cash proceeds received from the Reverse Recapitalization and PIPE Financing on Closing Date	$ 58,231
Less transaction costs previously deferred and netted against proceeds	(5,086)
Net cash proceeds from the Reverse Recapitalization and PIPE Financing	53,145

The total transaction costs of $11.1 million were related to third-party legal, accounting services and other professional services to consummate the Reverse Recapitalization and the PIPE Financing incurred by Old enGene. These transaction costs are allocated between common shares and additional paid-in capital, based on the relative fair value of the common shares and warrants issued upon the close of the Reverse Recapitalization, on the Company's consolidated balance sheet as the Company's common shares have no par value.

The following table summarizes the number of common shares outstanding immediately following the consummation of the Reverse Recapitalization and PIPE Financing transaction:

	Number of Shares
Old enGene Shareholders (Excluding Convertible Notes)	6,711,786
FEAC Shareholders, including sponsor's and shareholder with non-redemption agreement	3,670,927
Convertible Notes - Common Shares Issued	6,379,822
Common shares issued to PIPE Investors	6,435,441
Total common shares outstanding immediately after the Reverse Recapitalization and PIPE Financing	23,197,976

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Fair Value Measurements	12 Months Ended Oct. 31, 2024
Fair Value Disclosures [Abstract]	
Fair Value Measurements	

4. Fair Value Measurements

The Company did not have any financial assets or liabilities that required fair value measurement on a recurring basis as of October 31, 2023.

The following table presents the Company's fair value hierarchy for financial assets measured at fair value as of October 31, 2024:

		October 31, 2024		
Description	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Observable Inputs (Level 3)
Assets				
Cash equivalents				
Money market funds	121	121	—	—
U.S. government treasuries	94,236	94,236	—	—
Government agency securities	9,955	—	9,955	—
Short term marketable securities:				
U.S. government treasuries	51,574	51,574	—	—
Government agency securities	13,754	—	13,754	—
Long term marketable securities:				
U.S. government treasuries	49,627	49,627	—	—
Government agency securities	9,900	—	9,900	—
Total financial assets	$ 229,167	$ 195,558	$ 33,609	$ —

As of October 31, 2024, the Company classified its government agency marketable securities as Level 2 within the valuation hierarchy. The Company estimates the fair value of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly to estimate fair value. These inputs include market pricing based on real time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs.

During the years ended October 31, 2024 and 2023, there were no transfers or reclassifications between fair value measure levels of assets or liabilities. The carrying values of all other financial current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Convertible Debentures Embedded Derivative Liabilities

Prior to the Reverse Recapitalization, the Company's convertible debentures contained equity conversion options, and certain repayment features, that have been identified as a single compound embedded derivative requiring bifurcation from the host contract for the convertible debentures for which the fair value has not been elected. The Company estimated the fair value of the convertible debenture embedded derivative liabilities on issuance using a probability weighted scenario expected return model. The estimated probability and timing of underlying events triggering the conversion and liquidity repayment features and probability of exercise of the extension features within the convertible debentures as well as discount rates, volatility and share prices are inputs used to determine the estimated fair value of the embedded derivative.

The assumptions ranges that the Company used to determine the fair value of the convertible debentures embedded derivative liabilities for the 2022 Notes and BDC Notes that were outstanding as of each respective period (refer to Note 9, Notes Payable) were as follows:

	Immediately prior to settlement on October 31, 2023
Probability of qualified financing*	100 %
Volatility**	n/a
Class C Preferred Share price (CAD)**	n/a
Liquidity price at conversion of listing event***	$ 8.84
Fair value of common share at conversion of listing event***	$ 21.70
Discount rate****	18.4 %
Expected time to respective scenarios	0.0 years

* The probability represents the cumulated probabilities of conversion at various dates before maturity. The probability includes the probability of a SPAC transaction (which corresponds to a listing event for the 2022 Notes and to a liquidity event for the BDC Notes).

** Volatility and Class C Preferred share price is not applicable and expected time to scenario is 0.0 years as of October 31, 2023 as the 2022 Notes converted to shares upon the Reverse Recapitalization and the BDC Notes were repaid in full.

*** The liquidity price at the conversion of a listing event represents the conversion price of the 2022 Notes upon the merger with FEAC, and the fair value per common share at conversion of a listing event represents the quoted market price of the FEAC common shares on the close of the market on October 31, 2023, immediately prior to the settlement upon the completion of the Reverse Recapitalization.

**** Discount rate includes credit risk, discount for lack of marketability and other factors considered in the model.

Upon the close of the Reverse Recapitalization the 2022 Notes were converted and exchanged for common shares of the Company, resulting in an extinguishment of the 2022 Notes and related embedded derivative liability. Further the BDC Note (as defined below) was repaid in full. See Note 3, Reverse Recapitalization and Note 10, Convertible Debentures for additional detail. Immediately prior to the conversion and exchange of the 2022 Notes as part of the Reverse Recapitalization, the embedded derivative was measured to a fair value of $24.8 million. Further immediately prior to the repayment of the BDC Note, the embedded derivative liability was measured to a fair value of $0.4 million.

The following table provides a summary of the change in the estimated fair value of the Company's convertible debentures embedded derivative liabilities for the year ended October 31, 2023:

	Total
Balance as of October 31, 2022	3,791
Change in fair value of convertible debenture embedded derivative liabilities	21,421
Foreign exchange rate translation adjustment	5
Settlement of derivative liability in accordance with repayment and conversion of convertible debentures upon the consummation of the Reverse Recapitalization	(25,217)
Balance as of October 31, 2023	$ —

April 2023 Notes

The Company elected the fair value option of accounting for the April 2023 Notes. The Company recorded the April 2023 Notes at fair value upon the date of issuance, which was determined to be the total cash proceeds received of $8.0 million and was considered a Level 3 measurement within the fair value hierarchy. The April 2023 Notes were repaid through the issuance of $8.0 million in aggregate amount of convertible notes and warrants issued as part of the 2023 Financing. No change in fair value was recorded on the April 2023 Notes during the year ended October 31, 2023, given the close proximity between the issuance date of the notes and the repayment date. As of October 31, 2024 and 2023, the April 2023 Notes are no longer outstanding.

May 2023 Notes

The Company elected the fair value option of accounting for the May 2023 Notes. At issuance and for periods prior to the settlement of the May 2023 Notes, the Company estimated the fair value of the May 2023 Notes using a probability weighted scenario expected return model and was considered a Level 3 measurement per the fair value hierarchy. As part of the issuance of the May 2023 Notes, the Company also issued warrants which were determined to be freestanding, liability classified and measured at fair value. Refer below. The Company recorded both the May 2023 Notes and warrants issued as part of the 2023 Financing at fair value upon issuance, which totaled the amount of proceeds received on an aggregate basis, and subsequently remeasured the financial instruments to fair value at each reporting date.

The assumptions that the Company used to determine the fair value of the May 2023 Notes as of the issuance date are as follows:

		As of Issuance Date
Probability of qualified financing*		60 %
Volatility		85 %
Class C Preferred Share Price (CAD)	$	2.074
Liquidity price at conversion of listing event**	$	8.42
Fair value of common share at conversion of listing event**	$	10.25
Discount rate***		40.8 %
Expected time to respective scenarios		0.3 years

* The probability represents the cumulated probabilities of conversion at various dates before maturity. The probability includes the probability of a SPAC transaction (which corresponds to a listing event for the 2023 Notes).
** The liquidity price at the conversion of a listing event represents the conversion price of the 2023 Notes upon the merger with FEAC, and the fair value per common share at conversion of a listing event represents the price per share of the Newco upon the merger with FEAC, as set forth in the Merger Agreement.
*** Discount rate includes credit risk, discount for lack of marketability and other factors considered in the model.

Immediately prior to the conversion and exchange of the May 2023 Notes as part of the Reverse Recapitalization, the notes were remeasured to a fair value of $93.3 million. The fair value immediately prior to the settlement was determined using the quoted market price of $21.70 per share for the FEAC common shares on the close of business on October 31, 2023, which was determined to be fair value of the common share on settlement, and considering the 4,298,463 shares of the Company issued to the holders of the May 2023 Notes upon the consummation of the Reverse Recapitalization.

The following table provides a summary of the change in the estimated fair value of the Company's 2023 Notes for the year ended October 31, 2023. Upon the close of the Reverse Recapitalization the 2023 Notes were exchanged for common shares of the Company, resulting in an extinguishment of the 2023 Notes. See Note 3, Reverse Recapitalization and Note 10, Convertible Debentures.

		Total
Balance as of October 31, 2022	$	—
Issuance of May 2023 Notes		37,043
Change in fair value of May 2023 Notes		56,212
Settlement of 2023 Notes upon the consummation of the Reverse Recapitalization		(93,255)
Balance as of October 31, 2023	$	—

Warrant Liabilities

Prior to the consummation of the Reverse Recapitalization, Old enGene issued warrants to purchase redeemable convertible preferred shares as part of the issuance of certain redeemable convertible preferred shares, convertible debentures, and the term loan (the "Preferred Share Warrants"). Upon the close of the Reverse Recapitalization, the Preferred Share Warrants were surrendered for no consideration and the fair value was determined to be zero. The Company estimated the fair value of its Preferred Share Warrant liabilities using a Modified Black-Scholes option-pricing model, which included assumptions that are based on the individual characteristics of the Preferred Share Warrants on the valuation date, and assumptions related to the fair value of the underlying redeemable convertible preferred shares, expected volatility, expected life, dividends, risk-free interest rate and discount for lack of marketability ("DLOM"). Due to the nature of these inputs, the Preferred Share Warrants are considered a Level 3 liability.

The weighted average expected life of the Preferred Share Warrants was estimated based on the weighting of scenarios considering the probability of different terms up to the contractual term of 10 years in light of the expected timing of a future exit event, which includes a SPAC transaction. The Company determines the expected volatility based on an analysis of reported data for a group of guideline companies that have issued instruments with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. The risk-free interest rate is determined by reference to the Canadian treasury yield curve in effect at the time of measurement of the warrant liabilities for time periods approximately equal to the weighted average expected life of the warrants. The Company has not paid, and did not anticipate paying, cash dividends on its redeemable convertible preferred shares; therefore, the expected dividend yield is assumed to be zero.

Because there was no public market for the underlying redeemable convertible preferred shares, the Company determined their fair value based on third-party valuations. Initially, the estimated enterprise equity value of the Company was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Company's various securities of its capital structure using an option pricing method, or "OPM", and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another. Significant assumptions used in the OPM to determine the fair value of redeemable convertible preferred shares include volatility, DLOM, and the expected timing of a future liquidity event such as an IPO, SPAC transaction or sale of the Company, in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios.

In addition to considering the results of these valuations, the Company considered various objective and subjective factors to determine the fair value of the Company's preferred shares as of each valuation date, including the prices at which the Company sold redeemable convertible preferred in the most recent transactions, external market conditions, the progress of the Company's research and development programs, the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results, and the lack of an active public market for the Company's redeemable convertible preferred shares, among other factors.

The warrants issued by Old enGene as part of the 2023 Financing (the "2023 Warrants") were concluded to be freestanding, liability classified instruments upon issuance, which were subsequently reclassified to equity upon the consummation of the Reverse Recapitalization. See Note 10. The Company estimated the fair value of the 2023 Warrants based on the underlying quoted market price of the FEAC public warrants, prior to the close of the Reverse Recapitalization. The 2023 Warrants were classified as a Level 2 measurement given they are substantially similar to FEAC public warrants. The price used to value the 2023 Warrants as of the issuance date and immediately prior to the consummation of the Reverse Recapitalization was $0.53 and $0.74, per warrant, respectively, which represented the quoted market price of the FEAC public warrants on each date.

The following table provides a summary of the change in the estimated fair value of the Company's warrant liabilities for the year ended October 31, 2023:

		Total
Balance as of October 31, 2022		11,456
Warrant liability recognized upon issuance of May 2023 Notes		1,420
Change in fair value of warrant liabilities		(10,849)
Foreign exchange rate translation adjustment		(44)
Reclassification of 2023 Warrants to equity upon consummation of the Reverse Recapitalization		(1,983)
Balance as of October 31, 2023	$	—

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Marketable securities	**12 Months Ended Oct. 31, 2024**
Investments, Debt and Equity Securities [Abstract]	
Marketable securities	

5. Marketable securities

As of October 31, 2024, the marketable securities consisted of the following:

	October 31, 2024							
Description	**Amortized Cost**		**Unrealized Holdings Gains**		**Unrealized Holdings Losses**		**Aggregate Fair Value**	
Cash equivalents and short-term investments:								
Money market funds, included in cash and cash equivalents	$	121	$	—	$	—	$	121
US treasury		145,832		12		(30)		145,814
Government agency securities		23,714		3		(8)		23,709
Total cash equivalents and short-term investments	$	169,667	$	15	$	(38)	$	169,644
Long-term investments								
US treasury		49,931		—		(306)		49,625
Government agency securities		9,972		—		(74)		9,898
Total long-term investments	$	59,903	$	—	$	(380)	$	59,523
Total	$	229,570	$	15	$	(418)	$	229,167

As of October 31, 2024, all marketable securities held by the Company had remaining contractual maturities of one year and less, except for U.S. government securities that had maturities of one to two years.

As of October 31, 2024, the Company held 31 securities, 21 of which were in unrealized loss position. All investments in an unrealized loss position were in this position for less than 12 months. The Company does not intend to sell its investments before recovery of the amortized cost basis of its debt securities at maturity and no allowance for credit losses was recorded as of October 31, 2024 because the decline in fair value below amortized cost is not related to credit losses. Securities are evaluated at the end of each reporting period. The unrealized losses on U.S. Treasury and Government agency securities range from 0-1% of their amortized cost.

Accrued interest receivable on the Company's available-for-sale debt securities totaled $0.7 million and zero as of October 31, 2024 and 2023, respectively, and was presented within prepaids and other current assets on the Company's consolidated balance sheets. No accrued interest receivable was written off during the twelve months ended October 31, 2024 or 2023.

There were no material realized gains or losses recognized on the sale or maturity of available-for-sale securities during the years ended October 31, 2024 or 2023.

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Property and Equipment, Net	**12 Months Ended Oct. 31, 2024**
Property, Plant and Equipment [Abstract]	
Property and Equipment, Net	

6. Property and Equipment, Net

As of October 31, 2024 and 2023, property and equipment, consisted of the following:

	October 31, 2024	October 31, 2023
Lab equipment	$ 2,191	$ 1,779
Computer equipment	62	269
Computer software	146	70
Office furniture	141	69
Leasehold improvements	239	129
Property and equipment	2,779	2,316
Less: Accumulated depreciation and amortization	1,610	1,727
Property and equipment, net	$ 1,169	$ 589

Depreciation and amortization expense related to property and equipment was $0.3 million and $0.2 million for the year ended October 31, 2024 and 2023, respectively.

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Accrued Expenses and Other Current Liabilities

12 Months Ended

Oct. 31, 2024

Payables and Accruals [Abstract]

Accrued Expenses and Other Current Liabilities

7. Accrued Expenses and Other Current Liabilities

As of October 31, 2024 and 2023, accrued expenses and other current liabilities consisted of the following:

	October 31, 2024	October 31, 2023
Accrued research and development expenses	$ 3,773	$ 759
Employee compensation and related benefits	3,475	814
Accrued financing costs (1)	3,831	613
Professional fees	824	1,201
Accrued income taxes payable	-	39
Other	225	113
Total accrued expenses and other current liabilities	$ 12,128	$ 3,539

(1) The presentation of accrued financing costs as of October 31, 2023 has been updated to conform with presentation as of October 31, 2024.

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License Agreement and Clinical Research Organization

12 Months Ended

Oct. 31, 2024

License Agreement and Clinical Research Organization [Abstract]

License Agreement and Clinical Research Organization

8. License Agreement and Clinical Research Organization

License Agreement – Nature Technology Corporation

On April 10, 2020, the Company entered into a Non-Exclusive License Agreement (the “License Agreement”) with Nature Technology Corporation (“NTC”) whereby the Company licenses certain rights to Nanoplasmid™ technology from NTC for commercialization. Under the terms of the License Agreement, NTC granted to the Company and its affiliates a non-exclusive, royalty-bearing, sublicensable license to research, have researched, develop, have developed, make, have made, use, have used, import, have imported, sell, offer to sell, and have sold or offered for sale any product in the defined license field. Unless terminated earlier, the NTC license agreement will continue until no valid claim of any licensed patent exists in any country. The Company can voluntarily terminate the license agreement with prior notice to NTC.

The Company paid NTC an initial, upfront fee of $50 thousand which was recorded as research and development expense upon entering into the License Agreement. Beginning on the first anniversary of the effective date of the License Agreement and on each subsequent anniversary, the Company is required to pay NTC a $50 thousand annual maintenance fee. The Company is also required to make a payment to NTC of $50 thousand upon assigning the License Agreement to a third party.

The License Agreement provides for a one-time payment of $50 thousand for the first dose of a milestone product, as defined in the License Agreement, in the first patient in a Phase 1 clinical trial or, if there is no Phase 1 clinical trial, in a Phase 2 clinical trial, as well as a one-time payment of $450 thousand upon regulatory approval of a milestone product by the U.S. Food and Drug Administration. The first milestone related to the first dose of a milestone product, was achieved during the year ended October 31, 2021. The second milestone, regulatory approval of a milestone product, has not yet been achieved as of the year ended October 31, 2024. The Company is also required to pay NTC a royalty percentage in the low single digits of the aggregate net product sales in a calendar year by the Company, its affiliates or sublicensees on a product-by-product and country-by-country basis, as long as the composition or use of the applicable product is covered by a valid claim in the country where the net sales occurred. Royalty obligations under the license agreement will continue until the expiration of the last valid claim of a licensed patent covering such licensed product in such country.

In the event that the Company or any of its affiliates or sublicensees manufactures any Good Manufacturing Practice (“GMP”) lot of a product, then the Company or any such affiliate or sublicensee will be obligated to pay NTC an amount per manufactured gram of GMP (or its equivalent) lot of product, which varies based on the volume manufactured. The payment will expire on a product-by-product basis upon receipt of regulatory approval to market a product in any country in the licensed territory.

During each of the years ended October 31, 2024 and 2023, the Company incurred $50 thousand of expenses related to the annual maintenance fee under the License Agreement which is recorded within research and development expenses.

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Notes Payable

12 Months Ended

Oct. 31, 2024

Debt Disclosure [Abstract]

Notes Payable

9. Notes Payable

2021 Loan and Security Agreement

On December 30, 2021, the Company entered into a Loan and Security Agreement (the “Prior Loan Agreement”) with Hercules Capital, Inc. (“Hercules” or the “Lender”) for the issuance of a term loan facility with an aggregate principal amount of up to $20.0 million (the “Prior Term Loan”). The Prior Loan Agreement provided for (i) an initial term loan advance of $7.0 million, which closed on December 30, 2021, (ii) subject to the achievement of certain clinical milestones (“Clinical Milestone”), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $4.0 million from the achievement of the Clinical Milestone through June 15, 2022, which was drawn in June 2022, and (iii) subject to the achievement of certain financial milestones (“Financial Milestone”), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $9.0 million from achievement of the Financial Milestone through December 15, 2022, which was not achieved. The Company is required to pay an end of term fee (“Prior Term Loan End of Term Charge”) equal to 6.35% of the aggregate principal amount of the Prior Term Loan advances upon repayment.

The Prior Term Loans were scheduled to mature on July 1, 2025, with no option for extension (the “Prior Term Loan Maturity Date”).

The Prior Term Loan accrued interest at an annual rate equal to the greater of (i) 8.25% plus the prime rate of interest as reported in the Wall Street Journal minus 3.25% and (ii) 8.25% provided, that, from and after the date the Company achieves the financial milestone, as defined within the agreement, the reference to 8.25% in clauses (i) and (ii) is reduced to 8.15%. Borrowings under the Prior Term Loan are repayable in monthly interest-only payments through June 2023. After the interest-only payment period, borrowings under the Prior Term Loan are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. At the Company’s option, the Company may elect to prepay all, but not less than all, of the outstanding term loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% of the principal amount outstanding if the prepayment occurs in any of the first twelve months following the closing date of the last draw down; (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the closing date of the last draw down, but on or prior to twenty-four months following the closing date of the last draw down; and 1.0% of the principal amount outstanding at any time thereafter but prior to the Maturity Date.

In connection with the Prior Term Loan, the Company granted Hercules a security interest senior to any current and future debts and to any security interest, in all of the Company’s right, title, and interest in, to and under all of the Company’s property and other assets, and certain equity interests and accounts of Old enGene, subject to limited exceptions including the Company’s intellectual property. The Prior Loan Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company.

The debt discount and issuance costs under the Prior Term Loan were accreted to the principal amount of debt and being amortized from the date of issuance through the Maturity Date to interest expense using the effective-interest rate method. The effective interest rate of the outstanding debt under the Prior Loan Agreement was approximately 18.3% as of October 31, 2023.

The Company borrowed $11.0 million under the Prior Loan Agreement and incurred $1.1 million of debt discount and issuance costs inclusive of facilities fees, legal fees, Prior Term Loan End of Term Charge and initial fair value of the warrants under the Prior Term Loan.

Old Hercules Warrants

Under the Prior Loan Agreement, the Company agreed to issue to Hercules warrants (the “Old Hercules Warrants”) to purchase a number of shares of Old enGene’s redeemable convertible preferred shares at the exercise price equal to 2.5% of the aggregate amount of the Prior Term Loans that are funded, as such amounts are funded. On the first tranche closing, Old enGene issued a warrant to purchase 84,714 Class C Preferred Shares which were determined to have a fair value of $34 thousand upon issuance. On the second tranche closing, in June 2022, Old enGene issued an additional warrant to purchase 48,978 Class C Preferred Shares which were determined to have a fair value of $23 thousand upon issuance. The fair value of the Old Hercules Warrant values were initially recorded as a discount to the Prior Term Loan principal balance and are being amortized to interest expense using the effective interest method over the life of the Prior Term Loan.

The Old Hercules Warrants were initially exercisable for a period of ten years from the date of the issuance of each warrant at a per-share exercise price equal to $2.632 Canadian dollars, subject to certain adjustments as specified in the warrants. In addition, the Company has granted to the holders of the Old Hercules Warrants certain registration rights on a pari passu basis with the holders of outstanding preferred shares and warrants to purchase preferred shares.

The Company accounted for the warrants as a liability prior to the consummation of the Reverse Recapitalization since they were indexed to Old enGene’s redeemable convertible preferred shares that were classified as temporary equity. The Company remeasured the fair value of the warrants at each reporting date with changes being recorded as a change in the fair value of the warrant liabilities.

Upon the close of the Reverse Recapitalization, the Old Hercules Warrants, along with all other warrants to purchase shares of Old enGene's redeemable convertible preferred shares, were surrendered for no consideration.

Amended Loan and Security Agreement

On December 22, 2023 (the “Hercules Closing Date”), the Company entered into an amended and restated loan and security Agreement (the “Amended Loan Agreement”), with Hercules, as agent and lender, and the several banks and other financial institutions or entities from time to time parties thereto (with Hercules, the “Lenders”). The Amended Loan Agreement amends and restates in its entirety the Prior Loan Agreement with Hercules dated December 30, 2021.

As of October 31, 2024, the Amended Loan Agreement provides for a term loan facility of up to $50.0 million available in multiple tranches (the “Term Loan”), as follows: (i) an initial term loan advance (the “Tranche 1 Advance”) that was made on the Tranche 1 Advance closing of $22.5 million, approximately $8.6 million of which was applied to refinance in full the term loans outstanding under the Prior Loan Agreement, (ii) subject to the achievement of the specified Interim Milestone (the “Interim Milestone”), which includes no default or event of default, delivery of written notice to the Lenders that the Company has conducted an analysis of interim efficacy of data from the clinical evaluation of detalimogene in the Phase 2 clinical study, and satisfaction of certain other conditions precedent, a right of the Company to request that the Lenders make additional term loan advances to us in an aggregate principal amount of up to $7.5 million from the date of achievement of the Interim Milestone through the earlier of (x) 60 days following the achievement of the Interim Milestone and (y) March 31, 2025, and (iii) an uncommitted tranche subject to the Lenders’ investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time up to and including the Amortization Date (defined below) that the Lenders make additional term loan advances to the Company in an aggregate principal amount of up to $20.0 million. The Company is required to pay upon the earlier of January 1, 2028 (the “Maturity Date”) or payment in full of the Term Loans, an end of term fee equal to 5.50% of the aggregate principal amount of the Term Loans (the “End of Term Charge”). The Company is also required to pay on July 1, 2025 or, if earlier, the date the Company prepays the Term Loans, $0.7 million representing the Prior Term Loan End of Term Charge (the Prior Term Loan End of Term Charge and End of Term Charge, collectively the “End of Term Charges”).

The Term Loans mature on January 1, 2028, with no option for extension.

The Term Loan bears cash interest payable monthly at an annual rate equal to the greater of (a) the prime rate of interest as reported in the Wall Street Journal plus 0.75% (capped at 9.75%) and (b) 9.25%. The Term Loan also bears additional payment-in-kind interest at an annual rate of 1.15%, which is added to the outstanding principal balance of the Term Loan on each monthly interest payment date. Borrowings under the Amended Loan Agreement are repayable in monthly interest-only payments through the “Amortization Date”, which is either: (x) July 1, 2025 or (y) if the Interim Milestone is achieved and there has been no default, January 1, 2026, or (z) if the Interim Milestone and certain clinical milestones are achieved and there has been no default, July 1, 2026. After the Amortization Date, the outstanding Term Loans and interest shall be repayable in equal monthly payments of principal and accrued interest until the Maturity Date. The effective interest rate of the Term Loan was 11.63% as of October 31, 2024.

At the Company's option, the Company may elect to prepay all, but not less than all, of the outstanding Term Loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% of the principal amount outstanding if the prepayment occurs in any of the first twelve months following the Closing Date; (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the Closing Date but on or prior to twenty-four months following the Closing Date; and (iii) 1.0% of the principal amount outstanding if prepayment occurs at any time thereafter but prior to the Maturity Date.

In connection with the Amended Loan Agreement, the Company granted Hercules a security interest senior to any current and future debts and to any security interest in all of the Company’s right, title, and interest in, to and under all of the Company’s property and other assets, subject to limited exceptions including the Company’s intellectual property.

The Amended Loan Agreement contains negative covenants that, among other things and subject to certain exceptions, could restrict the Company's ability to incur additional liens, incur additional indebtedness, make investments, including acquisitions, engage in fundamental changes, sell or dispose of assets that constitute collateral, including certain intellectual property, pay dividends or make any distribution or payment on or redeem, retire or purchase any equity interests, amend, modify or waive certain material agreements or organizational documents and make payments of certain subordinated indebtedness. The Amended Loan Agreement also contains certain events of default and representations, warranties and non-financial covenants of the Company. The Company is in compliance with the financial covenants at October 31, 2024.

The Company accounted for the Amended Loan Agreement as an extinguishment of the Prior Term Loan. As a result of the extinguishment, the Company recorded a loss of $0.4 million as a component within other income and expense in the Company's consolidated statement of operations during the year ended October 31, 2024, which represented the difference between the reacquisition price of the debt, including fees and the initial fair value of the warrants paid directly to the lender, and the carrying value of the Prior Term Loan at the time of extinguishment.

As of October 31, 2024, the Company had borrowed $22.5 million under the Amended Loan Agreement and incurred $2.2 million of debt discount and issuance costs inclusive of legal fees and End of Term Charges under the Term Loan.

First Amendment to Amended and Restated Loan and Security Agreement

On December 18, 2024, the Company entered into the First Amendment to Amended and Restated Loan and Security Agreement with Hercules, which amended the Amended Loan Agreement. See Note 19, Subsequent Events for additional information.

Hercules Common Share Warrants

In connection with the Amended Loan Agreement, the Company also agreed to issue to the Lenders in connection with each advance of Term Loans warrants to purchase that number of the Company’s common shares, as shall be equal to 2% of the aggregate principal amount of such Term Loan advance divided by the Warrants per share exercise price of $7.21 (which exercise price equals the ten-day volume weighted average price for the ten (10) trading days preceding the Hercules Closing Date and is subject to customary adjustments under the terms of the Warrants) (the “Hercules Common Share Warrants”). The Hercules Common Share Warrants are exercisable for a period of seven years from issuance.

Under the terms of the Amended Loan Agreement, the maximum number of Hercules Common Share Warrants and underlying Common Shares of the Company that could be issued is 138,696. On the Hercules Closing Date, the Company issued to the Lenders 62,413 Hercules Common Share Warrants in connection with the Tranche 1 Advance of the Term Loans (the “Closing Date Warrants”). The Closing Date Warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Company’s Common Shares as prescribed by ASC 815. Upon entering into the Amended Loan Agreement, $0.3 million of the total $22.5 million Tranche 1 Advance was allocated to the warrants, on a relative fair value basis, and recorded within additional paid in capital.

Subsequently issued Hercules Common Share Warrants shall be substantially in the form of the Closing Date Warrants. Under the terms of the Amended Loan Agreement, the maximum number of Hercules Common Share Warrants and resultant underlying common shares of the Company that could be issued is 138,696 (i.e. 2% of the $50.0 million total commitment amount divided by the exercise price of $7.21 price specified in the Closing Date Warrant), assuming no adjustments are made under the terms of the Hercules Common Share Warrants and further assuming the full amount of Term Loans are drawn.

As of October 31, 2024 and 2023, the carrying value of the Term Loan consists of the following:

	October 31, 2024	October 31, 2023
Note payable, including End of Term Charge	$ 24,663	$ 10,144
Debt discount, net of accretion	(1,673)	(474)
Accrued interest	182	108
Note payable, net of discount	$ 23,172	$ 9,778

As of October 31, 2024, the Company classified $0.7 million of the note payable as current, which represents the back-end fee associated with the refinancing of the Prior Term Loan. As of October 31, 2023, the Company classified $0.6 million of the note payable as current, which represents the principal payments due and amortization of the debt discount between October 31, 2023 and the date the Term Loan was amended in December 2023, as the debt was refinanced on a long-term basis in the subsequent event period. During the years ended October 31, 2024 and 2023, the Company recognized $2.2 million and $1.8 million of interest expense related to the Amended Loan Agreement, respectively, of which $0.6 million and $0.4 million was related to the amortization of the debt discount, respectively.

Through October 31, 2024, the Company borrowed $22.5 million under the Amended Loan Agreement and incurred $2.2 million of debt discount and issuance costs inclusive of facility fees, legal fees, End of Term Charge and initial fair value of the warrants.

As of October 31, 2024, the estimated future principal payments due under the Loan Agreement, including the contractual End of Term Charge, are as follows:

	Note Principal Payments
2025	$ 699
2026	8,417
2027	10,987
2028	5,161
Total principal payments, including End of Term Charge	25,264

As of October 31, 2024, based on borrowing rates available to the Company for loans with similar terms and consideration of the Company’s credit risk, the carrying value of the Company’s variable interest rate debt, excluding unamortized debt issuance costs, approximates fair value.

April 2023 Notes

On April 4, 2023, Old enGene entered into a note purchase agreement (the “April 2023 Notes”) for a principal amount of $8.0 million with Merck Lumira Biosciences Fund, L.P., Merck Lumira Biosciences Fund (Quebec), L.P., Lumira Ventures III, L.P., Lumira Ventures III (International), L.P., Lumira Ventures IV, L.P., Lumira Ventures IV (International), L.P., Fond de solidarité des travailleurs du Québec (F.T.Q.), and Forbion Capital Fund III Cooperatief U.A. (collectively the “April 2023 Investors”). The April 2023 Notes had an interest free period of 45 days from the date of issuance, and commencing on the 46th day, began to accrue interest at a rate of 15% per annum. The April 2023 Notes were classified as current as they matured on the earlier of (i) July 31, 2023; or (ii) the date the Company completes a qualified financing, as defined within the April 2023 Notes as a financing pursuant to which the Company sells convertible promissory notes, warrants, preferred shares, common shares, or a combination thereof of the Company for an aggregate amount of at least $20.0 million. Upon the completion of the 2023 Financing (as defined below) in May 2023, Old enGene issued convertible debentures and warrants of Old enGene to the April 2023 Note investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing, as repayment of the April 2023 Notes.

The Company elected the fair value option of accounting for the April 2023 Notes. The Company recorded the April 2023 Notes at fair value upon the date of issuance, which was determined to be $8.0 million. Given the short period of time that the April 2023 Notes were outstanding, no change in fair value was recorded during the three months ended April 30, 2023. The April 2023 Notes were extinguished in May 2023 as part of the issuance of the May 2023 Notes. See Note 10, Convertible Debentures.

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Convertible Debentures	12 Months Ended Oct. 31, 2024
Debt Disclosure [Abstract]	
Convertible Debentures	

10. Convertible Debentures

Old enGene had issued convertible debentures to various investors. There was no outstanding principal, accrued interest, and unamortized deferred financing costs of the convertible debentures recorded on the balance sheet as of October 31, 2024 and October 31, 2023, as the convertible debentures were converted and exchanged for common shares of the Company or repaid upon the closing of the Reverse Recapitalization. See Note 3, Reverse Recapitalization.

BDC Notes

In September 2020, Old enGene issued a convertible debenture to the Business Development Bank of Canada (“BDC”) in the amount of $2.2 million (the “BDC Notes”). The debt bears interest at rate of 8% per annum and had an initial maturity date of September 28, 2023. In December 2021 Old enGene amended the agreement which resulted in the maturity date extending to September 29, 2025. The BDC Notes were convertible at the option of the holder into Old enGene's Class B redeemable convertible preferred shares at a price of 80% of the price paid per share in qualified financing, as defined within the BDC convertible debenture agreement. The issuance of the Prior Term Loan in 2021 met the definition of a qualified financing per the BDC convertible debenture agreement. As the conversion option was not exercised upon the issuance of the Prior Term Loan, the conversion rights upon a qualified financing were waived. There were optional conversion options that existed if Old enGene is in default, or in the event of certain liquidation events, as defined within the BDC Notes, which allow for conversion of the BDC Note into the most senior share outstanding at the time of the event. If a liquidation event, as defined within the BDC Note agreement, and which included a SPAC transaction, is consummated after a qualified financing, and optional conversion is not elected, the Company is required to pay the investor in cash, the outstanding principal and the accrued but unpaid interest and in addition an amount equal to 20% of the principal.

Upon issuance of the BDC Notes, the Company identified embedded derivatives related to the equity conversion features and liquidity event repayment features which required bifurcation as a single compound derivative instrument. The Company estimated the

fair value of the embedded derivative liabilities upon issuance at $0.2 million. The Company remeasured the fair value of the embedded derivatives in effect at each reporting period, with the subsequent changes in the fair value of the derivative being recognized in changes in fair value of derivatives within the Company's consolidated statements of operations and comprehensive loss. During the year ended October 31, 2023, the Company recorded a change in fair value of the convertible debentures embedded derivative liability associated with the BDC Note of $0.3 million. Total interest expense, including the amortization of debt discounts, of $0.3 million was recorded for the year ended October 31, 2023. Upon the close of the Reverse Recapitalization the Company repaid the BDC Note, including the liquidity event repayment amount, resulting in full settlement of the note and extinguishment of the embedded derivative liability. The estimated fair value of the embedded derivative liabilities at October 31, 2022 was $0.3 million, resulting in $0.3 million of expense recorded as change in fair value of convertible debentures embedded derivative liabilities in the consolidated statement of operations and comprehensive loss for the year ended October 31, 2022. Total interest expense, including the amortization of debt discounts, was $0.4 million for the year ended October 31, 2022. As part of the issuance of the BDC Notes, the Company incurred an aggregate of $36 of debt issuance costs of which a portion were recorded as a reduction of the carrying value of the BDC Notes, and a portion was allocated to the embedded derivative liabilities which were expensed as incurred.

On May 12, 2023, the Company consented to certain modifications of the BDC Notes pursuant to which the Company will be required on the Closing Date to repay in cash (i) the outstanding principal and the accrued but unpaid interest; and (ii) an amount equal to 20% of the principal.

Upon the close of the Reverse Recapitalization, the Company repaid the BDC Note in full, resulting in a loss on extinguishment of $9 thousand due to the difference between the repayment amount and the carrying amount of the debenture and fair value of the embedded derivative lability at the time of repayment.

2022 Notes

During the year ended October 31, 2022, Old enGene issued convertible debentures for an aggregate amount of $18.4 million on October 20, 2022 (the "2022 Notes"). The 2022 Notes had an initial maturity that is the later of (i) three years from the date of issuance; or (ii) the maturity date of the Prior Term Loan. See Note 8, License Agreement and Clinical Research Organization. The 2022 Notes bear interest at 10% per annum commencing on the date of issuance. The 2022 Notes are automatically convertible into common shares or redeemable convertible preferred shares of Old enGene upon certain events. Upon the close of the Reverse Recapitalization, the 2022 Notes were converted into 2,081,359 Common Shares of the Company.

Upon issuance of the 2022 Notes, the Company identified embedded derivatives related to the equity conversion features which required bifurcation as a single compound derivative instrument. The Company estimated the fair value of the embedded derivative liabilities upon issuance at $3.5 million. Given the close proximity between the issuance date of the notes and the Company's year ended October 31, 2022, no change in fair value was recorded related to the embedded derivative liabilities identified as part of the issuance of the 2022 Notes. During the year ended October 31, 2023, the Company recorded a change in fair value associated with the 2022 Notes embedded derivative liability of $21.2 million in the consolidated statement of operations and comprehensive loss for the year ended October 31, 2023. As of October 31, 2023 no embedded derivative liability is recorded for the 2022 Notes as they converted to shares of the Company upon the consummation of the Reverse Recapitalization. Total interest expense, including the amortization of debt discounts, was $2.8 million for the year ended October 31, 2023, respectively. As part of the issuance of the 2022 Notes, the Company incurred an aggregate of $44 thousand of debt issuance costs of which a portion were recorded as a reduction of the carrying value of the 2022 Notes, and a portion was allocated to the embedded derivative liabilities which were expensed as incurred.

On May 16, 2023, the Company agreed to certain modifications of the 2022 Notes having an aggregate principal amount of $18.4 million (the "Amended 2022 Financing"), which included a change in the definition of the maturity date by allowing an extension of the maturity date upon election of a noteholder majority, increasing the percentage required for a noteholder majority, and modifying terms of certain conversion options. The amendments to the 2022 Notes did not result in the addition or termination of any substantive conversion terms, and the amendment to the 2022 Notes was determined to be non-substantial and was accounted for as a modification. In addition, as part of the May 2023 Financing, the holders of the 2022 Notes which participated in the 2023 Financing received warrants to purchase common shares of the Company. The fair value of the warrants at the time of issuance to the holders of the 2022 Notes was determined to be $0.5 million and was recorded as reduction of the carrying value of the 2022 Notes as part of the modification, which is being amortized to interest expense through the maturity date of the 2022 Notes.

On October 31, 2023 upon the close of the Reverse Recapitalization, the 2022 Notes were converted into 2,081,359 Common Shares of the Company. The Company accounted for the conversion as an extinguishment and recorded a loss on extinguishment of

$3.1 million, relating to the difference between the fair value of the common shares issued and the carrying value of the 2022 Notes and fair value of the embedded derivative liability at the time of conversion.

May 2023 Notes

On May 16, 2023, concurrently with the execution and delivery of the Merger Agreement, Old enGene entered into agreements pursuant to which it agreed to issue new convertible notes and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in repayment of the April 2023 Notes in an aggregate amount of $8.0 million (collectively, the "May 2023 Notes" and, together with the warrants purchased concurrently, the "2023 Financing"; the 2023 Financing together with the Amended 2022 Financing, the "Convertible Bridge Financing").

The 2023 Financing occurred in two separate issuances with $28.0 million issued in May 2023 for $20.0 million in cash and $8.0 million in repayment of the April 2023 Notes, and an additional $10.0 million issued in June 2023 for $10.0 million in cash, of which Forbion Growth Sponsor FEAC I B.V. funded an aggregate amount of $20.0 million of the total $38.0 million. The May 2023 Notes issued as part of the 2023 Financing, if not converted, have an initial maturity date of October 20, 2025 and are to accrue interest at 10% per annum, which is payable upon maturity.

The warrants issued as part of the 2023 Financing were for the purchase of common shares of Old enGene. The 2023 Warrants were only to become exercisable upon the completion of the merger. Upon the close of the Reverse Recapitalization, the 2023 Warrants were exchanged for 2,679,432 warrants of the Company and have the same terms as the public warrants issued upon the FEAC initial public offering, with an exercise price of $11.50, and which will expire five years after the completion of the merger.

The warrants issued as part of the 2023 Financing were concluded to be liability classified upon issuance, as they failed the fixed for fixed criteria that is required for a contract to be considered indexed to the Company's own stock as prescribed by ASC 815. The terms of the warrants initially required the Company to issue a variable number of shares until the PIPE Financing was executed, at which time the number of warrants became fixed. The 2023 Warrants were initially and subsequently measured at fair value with any changes in fair value recorded as a component of other income and expense within the change in fair value of warrant liabilities. See Note 3, Reverse Recapitalization. Upon the execution of the PIPE Financing and consummation of the Reverse Recapitalization, the warrants were reclassified to equity as the number of warrants became fixed and it was determined that the warrants met the fixed for fixed criteria that is required for a contract to be considered indexed to the Company's own stock as prescribed by ASC 815.

The Company elected the fair value option of accounting for the May 2023 Notes. The Company recorded May 2023 Notes at fair value upon the date of issuance. At inception the fair value of the May 2023 Notes was determined to be $37.0 million and the fair value of the related warrants was determined to be $1.4 million, of which $0.5 million related to the fair value of the warrants issued to the holders of the 2022 Notes, as described above. During the year ended October 31, 2023, the Company recorded a change in fair value of the May 2023 Notes of $56.2 million. The Company incurred $0.8 million of debt issuance costs associated with the May 2023 Notes which have been expensed and are included within general and administrative expenses. See Note 3, Reverse Recapitalization.

On October 31, 2023 upon the close of the Reverse Recapitalization, the 2023 Notes were converted into 4,298,463 common shares of the Company. The Company accounted for the conversion as an extinguishment, with no gain or loss recorded on extinguishment as the fair value of the common shares issued was determined to equal the fair value of the 2023 Notes at the time of conversion.

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Redeemable Convertible Preferred Shares	12 Months Ended Oct. 31, 2024
Equity [Abstract]	
Redeemable Convertible Preferred Shares	

11. Redeemable Convertible Preferred Shares

As of October 31, 2022, Old enGene's Articles of Amendment had an unlimited number of authorized shares of each class of redeemable convertible preferred shares.

Class A Redeemable Convertible Preferred Shares

On July 26, 2013, the Company entered into a subscription agreement (the "Class A Agreement") with multiple investors, whereby the Company agreed to sell to the investors an initial aggregate amount of 610,333 Class A redeemable convertible preferred shares at a price of $1.5929 ($1.63845 CAD) per share for total aggregate proceeds of $1.0 million (the "Class A Initial Closing"). Included within the Class A Agreement were three additional future tranche obligations (the "Class A Second Tranche," "Class A Third Tranche" and "Class A Fourth Tranche") for the Company to issue and sell shares of Class A redeemable convertible preferred shares upon the achievement of certain milestone events. Only the Class A Second Tranche closed under the Class A Agreement. The Class A Second Tranche obligated the Company to sell and the Class A Investors to purchase 1,830,999 shares of Class A redeemable convertible preferred shares at a price of $1.56967 ($1.63845 CAD) per share for total proceeds of $2.9 million, upon the establishment of the

Company's headquarters in Montreal Quebec and completion of experiments required to bolster a patent application for dually-derivatized chitosan (the "Second Closing Milestone Event"), which occurred in 2013. Additionally, upon completing the Class A redeemable convertible preferred share financing, convertible notes of the Company held by multiple investors converted into Class A redeemable convertible preferred shares.

Class B Redeemable Convertible Preferred Shares

On January 6, 2015, the Company entered into a subscription agreement (the "Class B Agreement") with multiple investors, where the Company agreed to sell to the investors an initial aggregate amount of 2,758,221 Class B redeemable convertible preferred shares at a price of $1.85032 ($2.17532 CAD) per share for total proceeds of $5.1 million (the "Class B Initial Closing"). Included within the Class B Agreement were two additional closings (the "Class B Second Tranche," and the "Class B Third Tranche," respectively) which obligated the Company to sell and Class B investors to purchase additional Class B redeemable convertible preferred shares upon certain events. The Class B Second Tranche obligated the Company to sell and the Class B Investors to purchase 1,838,815 Class B Shares at a price of $1.63419 ($2.17532 CAD) per share for total proceeds of $3.0 million and the Class B Third Tranche obligated the Company the sell and the Class B Investors to purchase 1,608,963 Class B Shares at a price of $1.63419 ($2.17532 CAD) per share for total proceeds of $2.6 million. The Class B Second Tranche and Class B Third Tranche closed on March 1, 2017.

Class B-1 Redeemable Convertible Preferred Shares

On September 10, 2015, the Company entered into a Subscription Agreement (the Class "B-1 Agreement"), in which the Company was to issue 1,523,809 Class B-1 redeemable convertible preferred shares for a purchase price of $1.64367 ($2.17532 CAD) per share, resulting in aggregate proceeds of $2.5 million. During the year ended October 31, 2020, the Class B-1 redeemable convertible preferred shares converted to common shares on a 1:1 basis. Therefore, as of each of the years ended October 31, 2023, October 31, 2022, and October 31, 2021, no shares of the Class B-1 redeemable convertible preferred shares remained outstanding. The Company presented these shares within temporary equity, as they contained the same redemption features as the Class B redeemable convertible preferred shares (further described above). Upon conversion to common shares, the carrying value of the Class B-1 redeemable convertible preferred shares was reclassified to additional paid in capital within shareholders' deficit.

Class C Redeemable Convertible Preferred Shares

The Class C redeemable convertible preferred shares are issuable in series, of which an unlimited number are designated as Series 1 Class C redeemable convertible preferred shares with an issue price per share of $1.5929 ($1.63845 CAD); an unlimited number are designated as Series 2 Class C redeemable convertible preferred shares with an issue price per share of $1.85032 ($2.175315 CAD); an unlimited number are designated as Series 3 Class C redeemable convertible preferred shares with an issue price per share of $2.12376 ($2.6320 CAD); and an unlimited number are designated as Series 4 Class C redeemable convertible preferred shares that is reserved for the potential conversion of the BDC Notes, and will each have an issue price per share of $1.69901 ($2.10559 CAD).

On June 30, 2021, the Company entered into a subscription agreement (the "Class C Agreement") with multiple investors, where the Company agreed to sell to the Investors an initial aggregate amount of 3,662,813 Series 3 Class C redeemable convertible preferred shares (the "Series 3 Class C Shares") at a price of $2.12376 ($2.6320 CAD) per share for total proceeds of $7.8 million (the "Class C Initial Closing"). Included within the Class C Agreement was one additional closing (the "Class C Second Tranche") which obligated the Company to sell and Class C investors to purchase additional Class C redeemable convertible preferred shares upon the achievement of certain milestone events. The Class C Second Tranche obligated the Company to sell and the Class C investors to purchase 3,662,810 Series 3 Class C Shares at a price of $2.13192 ($2.6320 CAD) per share for total proceeds of $7.8 million. The Class C Second Tranche closed on October 29, 2021.

As part of each of the Class C Initial Closing and Class C Second Tranche, each Class C investor received 3,662,813 and 3,662,810 warrants, respectively, to purchase Class C redeemable convertible preferred shares (the "Class C Warrants"), resulting in an aggregate issued amount of 7,325,623 Class C Warrants. The Class C Warrants have an exercise price of $2.12376 ($2.6320 CAD) per share and a term of 10 years. The Class C Warrants were determined to be liabilities. The Company estimated the fair value of the warrant liabilities upon issuance and remeasured the fair value of the warrant liabilities at each reporting period, with the subsequent changes in the fair value of the warrant liabilities being recognized in changes in fair value of warrant liabilities within the Company's consolidated statements of operations and comprehensive loss. Upon the completion of the merger with FEAC, all existing Class C Warrants of the Company will be extinguished.

Under the terms of the Class C Agreement, certain convertible notes held by various Class C investors and other investors were exchanged for an aggregate amount of 16,464,646 Class B redeemable convertible preferred shares. Additionally, upon entering into the Class C Agreement, the Company also entered into a share exchange agreement (the "Share Exchange Agreement") with the Class A investors and the Class B investors. As part of the Share Exchange Agreement, certain of the Class A redeemable convertible preferred shares issued to Class A investors were exchanged for Series 1 Class C redeemable convertible preferred shares and certain of the Class B redeemable convertible preferred shares issued to the Class B investors were exchanged for Series 2 Class C redeemable convertible preferred shares. This exchange resulted in the derecognition of Class A and B redeemable convertible preferred shares and the recognition of Class C redeemable convertible preferred shares at the fair value of the Class C redeemable convertible preferred shares. The difference between the carrying value of the Class A and Class B redeemable convertible preferred shares and the fair value of the Class C redeemable convertible preferred shares for which they converted into was recorded within additional paid in capital and no gain or loss on extinguishment was recorded within the consolidated statements of operations and comprehensive loss. Further, the February 2020 Warrants, June 2020 Warrants, and 2021 Warrants, which consisted of warrants to purchase the Company's Class B redeemable convertible preferred shares and were issued as part of the convertible debentures were cancelled and replaced by the terms of the Class C Warrants. The aggregate amount of outstanding warrants of 10,242,130 from the February 2020 Warrants, the June 2020 Warrants, and the 2021 Warrants converted into 10,242,130 Class C Warrants, which have an exercise price of $2.12376 ($2.6320 CAD) per share and a term expiring on February 14, 2030. Immediately prior to conversion, the warrants were marked to fair value, with the change in the fair value of the warrant liabilities being recognized in changes in fair value of warrant liabilities within the Company's consolidated statements of operations and comprehensive loss.

Upon issuance of each series of Class A, Class B, and Class C Preferred Shares, the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features.

Conversion of Redeemable Convertible Preferred Stock

Pursuant to the terms of the Merger Agreement, upon the consummation of the Reverse Recapitalization, each share of Old enGene's redeemable convertible preferred stock issued and outstanding immediately prior to the close was exchanged for common shares of the Company using the Company Exchange Ratio of approximately 0.18048. A retrospective adjustment has been applied to all periods presented to reflect the Reverse Recapitalization. See Note 3, Reverse Recapitalization for additional discussion.

Undesignated Preferred Stock

The Company's Certificate of Incorporation, as amended and restated, authorizes the Company to issue an unlimited number of preferred shares with no par value. The shares of preferred stock are currently undesignated.

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Common Shares

12 Months Ended
Oct. 31, 2024

Equity [Abstract]

Common Shares

12. Common Shares

The Company has an unlimited number of authorized shares of Common Shares, with no par value. As of October 31, 2024 and 2023 there were 50,976,676 and 23,197,976 common shares outstanding, respectively.

The holders of the Common Shares are entitled to one vote for each Common Share held on all matters submitted to a vote of shareholders. Common shareholders are entitled to receive dividends, as may be declared by the Board of Directors, if any, subject to the preferential dividend rights of preferred stock. Through October 31, 2024, no cash dividends had been declared or paid.

On February 13, 2024, the Company entered into subscription agreements (collectively, the "February 2024 Subscription Agreements") with the investors named therein, for the private placement (the "February 2024 PIPE Financing") of 20,000,000 common shares of the Company, at a price of $10.00 per share. The aggregate gross proceeds from the February 2024 PIPE Financing was $200 million, before deducting offering expenses of $12.4 million. The February 2024 PIPE Financing closed on February 20, 2024.

On October 24, 2024, the Company entered into subscription agreements (collectively, the "October 2024 Subscription Agreements") with the investors named therein, for the private placement (the "October 2024 PIPE Financing") of 6,758,311 common shares of the Company, at a price of $8.90 per share. The aggregate gross proceeds from the October 2024 PIPE Financing was $60.1 million, before deducting offering expenses of $3.8 million. The October 2024 PIPE Financing closed on October 29, 2024.

Common share warrants

As of October 31, 2024 and 2023, the Company had 8,511,968 and 10,411,641 warrants to purchase Common Shares outstanding, respectively.

Of the warrants to purchase Common Shares outstanding as of October 31, 2024, 8,449,555 have the same terms as the FEAC public warrants issued in connection with FEAC's IPO, and have an exercise price of $11.50, and are exercisable beginning 30 days after the completion of the Reverse Recapitalization and which will expire on October 31, 2028, or five years after the completion of the Reverse Recapitalization. Through October 31, 2024, 383,355 common shares have been issued as a result of the exercise of 1,379,391 warrants on a cashless basis and 520,282 common shares have been issued through cash exercises of warrants for proceeds totaling $6.0 million.

The number of Common Shares to be issued upon the cashless exercise is equal to the quotient obtained by dividing (x) the product of the number of shares underlying the warrants, multiplied by the excess of the "Fair Market Value" over the warrant exercise price of $11.50 by (y) the Fair Market Value. The Fair Market Value is the volume weighted average price of the shares for the ten (10) trading day period ending on the trading day prior to the date that notice of exercise is received by the Company's Warrant Agent from the holder or its broker or intermediary. The warrants had a cashless exercise period until such time as the registration statement under the Securities Act with respect to the enGene Common Shares underlying the enGene Warrants was declared effective, which occurred on March 5, 2024. The Company may elect to call in the warrants for redemption if the share price of the Company equals or exceeds $18.00 for any twenty (20) trading days within the thirty (30) trading-day period ending on the third (3rd) trading day prior to the date on which notice of the redemption is given, subject to adjustments as provided in the terms of the warrant agreement.

The common share warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Company's common shares as prescribed by ASC 815.

As described in Note 9, Notes Payable, the additional 62,413 of the warrants to purchase Common Shares outstanding as of October 31, 2024, were issued as part of the Amended Term Loan on December 22, 2023, have an exercise price of $7.21, and are exercisable at any time beginning on December 22, 2023 expiring on December 22, 2030, or seven years from the issuance date. The common share warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Company's common shares as prescribed by ASC 815.

As of October 31, 2024, and 2023, the Company has reserved the following Common Shares for the exercise of Common Share warrants, share options, and remaining shares reserved for future issuance under the Company's 2023 Plan (as defined below):

	October 31, 2024	October 31, 2023
Warrants to purchase common shares	8,511,968	10,411,641
Options to purchase common shares	6,034,512	2,706,941
Remaining shares reserved for future issuance under the equity plans	2,752,889	2,607,943
Total	17,299,369	15,726,525

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Share-Based Compensation

12 Months Ended
Oct. 31, 2024

Share-Based Payment Arrangement [Abstract]

Share-Based Compensation

13. Share-Based Compensation

Pursuant to the terms of the Reverse Recapitalization, upon the Closing Date, each outstanding option to purchase Old enGene's common stock issued under the Old Plan's was exchanged for an option to purchase common shares of the Company, and the number of shares and exercise price of each granted option was adjusted using the exchange ratio of approximately 0.18048. Further, the currency of all exercise prices of the options issued under the Old Plans were converted from CAD to USD using the exchange rate in effect on the day immediately prior to the Closing Date. A retrospective adjustment has been applied to the number of options and exercise price of stock options for all periods presented to reflect the Reverse Recapitalization as discussed further in Note 3.

The Old Plans

Old enGene had an employee share option plan (the "ESOP") and an equity incentive plan (the "EIP") (collectively, the " Old Plans") which was adopted by the Board of Directors, and approved by the shareholders, effective July 5, 2018.

Under the Old Plans, options to purchase non-voting common shares of Old enGene's shares may be granted to directors, officers, employees, consultants and members of the scientific advisory board. The Old Plans provide for the issuance of common stock options up to a maximum of 15% of the aggregate issued and outstanding common shares and non-voting common shares of Old enGene calculated on an as converted and fully diluted basis. The Old Plans were administered by Old enGene's Board of Directors. Old enGene's Board of Directors determined the number of options to be granted, the vesting period and the exercise price of new options. It was Old enGene's policy to establish the exercise price at an amount that approximates the fair value of the underlying shares on the date of grant as determined by Old enGene's Board of Directors. The options vest in accordance with the vesting terms determined for each grant by Old enGene's Board of Directors. The vesting terms of Old enGene's granted stock options with service only conditions are typically 100% vesting immediately upon grant date, or over a three- or four-year service period. Upon the consummation of the Reverse Recapitalization, the Company recognized share-based compensation expense of $0.4 million associated with the acceleration of the vesting for the outstanding awards with service only vesting conditions under the Old Plan. As of October 31, 2024 and 2023, no unrecognized compensation cost remains for the outstanding awards granted under the Old Plan with service only vesting conditions.

On July 7, 2023, the Board of Directors approved the reservation of an additional 1,046,764 non-voting common shares for issuance under the Company's employee equity incentive plan, revising the number of shares reserved from 1,775,729 to 2,822,493. Also on July 7, 2023, the Company granted 1,046,764 options to employees at an exercise price of $5.87 CAD ($4.24 USD). These options are not exercisable unless and until the completion of the Reverse Recapitalization and there is an effective registration statement for the shares underlying such granted options and will terminate automatically in the event of the termination of the Merger Agreement. The Company has valued these awards at the grant date using Black-Scholes pricing model in which the fair value of the stock on the grant date was equal to the exercise price of the award. The expected term has been determined using management's best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, if any, and comparison to expected terms used by peers. Upon the grant date, 794,643 of the issued options were fully vested, and the remaining 252,121 options will vest over varying terms up to four years on a pro rata basis. The Company recognizes compensation expense when achievement of the performance condition is deemed probable using an accelerated attribution method, as if each vesting tranche was treated as an individual award. During the year ended October 31, 2023, $2.6 million of stock based compensation expense was recorded associated with the 1,046,764 stock options granted in July 2023 because the Reverse Recapitalization was completed and the Company determined that the filing of the registration statement was probable to occur.

Upon the consummation of the Reverse Recapitalization on October 31, 2023, all options outstanding under the Old Plans were exchanged for 2,706,941 shares options to purchase common shares of the Company based on the Exchange Ratio determined in accordance with the terms of the Merger Agreement. Further, all exercise prices were adjusted by the Exchange Ratio and the currency of the exercise prices was changed from CAD to USD based on the exchange rate in effect on October 30, 2023, the day immediately before the consummation of the Reverse Recapitalization. No incremental compensation cost was recorded as a result of the change in underlying common shares from Old enGene to the Company, or as a result of the change of the exercise prices to reflect the adjustment for the Exchange Ratio and the change in currency from CAD to USD, as it was concluded that the fair value of the awards immediately before and immediately after the modifications did not change. No options remain available for grant under the Old Plans as of October 31, 2023.

The 2023 Plan

On October 31, 2023, upon the completion of the Reverse Recapitalization, the shareholders approved and the Company adopted the enGene Holdings Inc. 2023 Incentive Equity Plan (the "2023 Plan"), which superseded the Old Plans. The 2023 Plan authorizes the award of incentive stock options, or ISOs, non-qualified stock options, or NQSOs, Stock Units, Stock Appreciation Rights, or SARs, and other share-based awards including performance awards and share bonus awards.

The number of shares initially reserved for issuance under the 2023 Plan is 2,607,943 Common Shares, plus 2,706,941 common shares subject to the outstanding grants under the Old Plans, and shall automatically increase on January 1 of each calendar year beginning in 2024 by a number of shares equal to the lesser of 1,946,226 Common Shares and such lesser number as may be determined by the Board. The Common Shares authorized under the 2023 Plan increased by 1,946,226 on January 2, 2024. As of October 31, 2024, the total number of Common Shares reserved for issuance under the 2023 Plan is 7,261,110, and there are 2,752,889 shares remaining for issuance.

The 2023 Plan is administered by the Board or, at the discretion of the Board, by a committee of the Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the Common Shares on the date of grant and the term of stock option may not be greater than ten years. Common Shares that are expired terminated, surrendered or cancelled under the 2023 Plan without having been fully exercised will be available for future awards.

On May 15, 2024, the shareholders of the Company approved changes to the 2023 Plan. The original 2023 Plan contained an evergreen provision (the "Evergreen Provision") pursuant to which, commencing with the first business day of each calendar year beginning in 2024, the aggregate number of the Company's Common Shares that could be issued or transferred thereunder (the "Plan Share Reserve") and the number of Common Shares available for options intended to qualify as incentive stock options (the "ISO Sublimit") each increased by a number of Common Shares equal to the lesser of (x) 1,946,226 Common Shares and (y) such lesser number of Common Shares as may be determined by the Compensation Committee. Pursuant to the Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan, on May 15, 2024, the Evergreen Provision was amended to provide for annual increases on the first business day of each calendar year of (i) the Plan Share Reserve by such number of Common Shares as equals 5% of the aggregate number of Common Shares outstanding on the final day of the immediately preceding calendar year (or such smaller number of shares as is determined by the compensation committee), and (ii) the ISO Sublimit by the lesser of 2,500,000 Common Shares and the increase in the Plan Share Reserve (or such smaller number of shares may be determined by the compensation committee of the Company's board of directors).

Inducement Grants

Pursuant to the Nasdaq inducement grant exception, during the year ended October 31, 2024, the Company issued options to purchase an aggregate of 1,643,000 Common Shares to certain new hire employees at a weighted-average exercise price of $8.69 per share. These options were granted outside of the Company's 2023 Plan. The options awarded have an exercise price equal to the closing stock price of the Company on the date of the grant and vest over four years, with 25% of the underlying shares vesting on the one-year anniversary of the grant date and the remainder vesting in equal amounts monthly for three years thereafter, subject continued service as an employee. The options have a term of 10 years from the date of the grant.

As of October 31, 2024, none of the awards granted under the Inducement Grants have vested, expired, or been forfeited, and all options remain outstanding.

Stock Options

The assumptions that the Company used to determine the grant-date fair value of stock options during the years ended October 31, 2024 and 2023, were as follows:

	Year ended October 31, 2024	Year ended October 31, 2023
Expected term (in years)	5.51-6.08	5.2 – 6.08
Expected volatility	78.24-82.33%	79.92 – 81.48%
Risk-free interest rate	1.78-4.66%	3.56 – 4.35%
Expected dividend yield	—	—
Fair value of common shares and exercise price of options (CAD)	$ N/A	$ 2.11 – 12.36
Fair value of common shares and exercise price of options (USD)	$ 4.73-12.60	$ 1.52 – 8.93

The following table summarizes the Company's stock option activity:

	Number of Shares	Weighted-Average Exercise Price (USD)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of October 31, 2023	2,706,941	$ 2.40	8.1	$ 52,192
Granted	3,591,200	10.18		
Exercised	(116,752)	0.97		
Forfeited or expired	(146,877)	6.71		
Outstanding as of October 31, 2024	6,034,512	$ 6.88	7.4	$ 17,809
Options vested and exercisable as of October 31, 2024	2,497,082	$ 2.32	4.4	$ 16,311
Options unvested as of October 31, 2024	3,537,430	$ 10.10	9.6	$ 1,498

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's common share as of each reporting period.

The weighted-average grant-date fair value per share of share options granted during the years ended October 31, 2024 and 2023 was $7.30 and $2.96, respectively.

Modification of Employment Agreements

On February 13, 2024, the Company entered into a Transition and Modified Employment Agreement (the "Transition Agreement") with the Company's former Chief Executive Officer, Jason Hanson, which amends and modifies the CEO's Employment Agreement dated November 8, 2023 (the "Amended Employment Agreement"). Under the terms of the Amended Employment Agreement Mr. Hanson will be entitled to:

(i) twelve months of continued health insurance benefits;

(ii) payment of a 2024 target annual bonus in the amount of $390,000, less applicable taxes and withholdings;

(iii) acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination; and

(iv) extension of the period to exercise his vested equity awards to three years following the later of date of termination of his employment or the date of termination of the Consulting Period (as defined below), but in no event shall the post-termination exercise period of the CEO's vested equity awards extend beyond the respective applicable term thereof.

The Transition Agreement further provided that, in the e2,vent Mr. Hanson were to resign upon the appointment by the Company of a new chief executive officer, Mr. Hanson would be immediately engaged in a consulting role to provide transition services as a Senior Strategic Advisor to the Company for a period of at least six months following the effective date of resignation (the "Consulting Period") in exchange for a monthly fee of $25,000 for the initial six-month Consulting Period, and $500 per hour thereafter, provided that Mr. Hanson need not devote more than fifteen (15) hours per week to providing such transition services.

Under the Transition Agreement, the 1,216,266 stock option awards issued to Mr. Hanson were modified to allow for an extended exercise period as described above. The modification resulted in an incremental share-based compensation expense of $1.0 million which was recorded upon the effective date of the Transition Agreement.

Mr. Hanson resigned effective as of July 19, 2024 in connection with the Company's appointment of a new chief executive officer. On July 20, 2024, enGene appointed Ronald H. W. Cooper as Chief Executive Officer of the Company and as director of the Company's Board of Directors.

Additionally, in 2024, the Company entered into a Severance Agreement with each of three former employees, including the former Chief Medical Officer and the former Chief Scientific Officer. Under the terms of Severance Agreement, the employees are entitled to twelve months of continued pay and health insurance benefits; a payment of a 2024 target annual bonus prorated through the last day of employment, acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination and an extended expiry period, which resulted in a stock-based compensation modification. Under the terms of the agreements, 231,684 stock option awards were modified to allow for an extended exercise period as described above. As of October 31, 2024, the Company recognized incremental stock-based compensation expense of $0.3 million related to the severance agreements.

Share-based Compensation Expense

Share-based compensation expense included in the Company's consolidated statements of operations and comprehensive loss was as follows:

	Year Ended October 31, 2024	Year Ended October 31, 2023
Research and development	$ 1,794	$ 780
General and administrative	3,530	2,670
Total share-based compensation expense	$ 5,324	$ 3,450

As of October 31, 2024, there was $22.1 million of unrecognized compensation, which is expected to be recognized over a weighted-average period of 3.47 years.

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Net Loss Per Share	**12 Months Ended Oct. 31, 2024**

Earnings Per Share [Abstract]

Net Loss Per Share

14. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share for the periods presented, retrospectively restated to reflect the exchange of shares upon the close of the Reverse Recapitalization:

	Year Ended October 31, 2024	Year Ended October 31, 2023
Numerator:		
Net loss	$ 55,142	$ 99,917
Deemed dividend attributable to redeemable convertible preferred shareholders	—	4,822
Net loss attributable to common shareholders, basic and diluted	$ 55,142	$ 104,739
Denominator:		
Weighted-average number of common shares used in net loss per share, basic and diluted	37,782,346	692,609
Net loss per common share, basic and diluted	$ 1.46	$ 151.22

The Company excluded the following shares from the computation of diluted net loss per share attributable to common shareholders during the year ended October 31, 2024, and 2023 because including them would have had an anti-dilutive effect:

	Year Ended October 31,	
	2024	2023
Warrants to purchase common shares	8,511,968	10,411,641
Options to purchase common shares	6,034,512	2,706,941
Total	14,546,480	13,118,582

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Income Taxes	12 Months Ended Oct. 31, 2024

Income Tax Disclosure [Abstract]

Income Taxes

15. Income Taxes

Loss before provision for income taxes consisted of the following:

	Year ended October 31,	
	2024	2023
Domestic (Canada)	$ (53,460)	$ (99,157)
Foreign (US)	(1,701)	(743)
Loss before income taxes	$ (55,161)	$ (99,900)

The components of the provision for (recovery of) income taxes is as follows:

	Year ended October 31,	
	2024	2023
Current expense (benefit):		
Domestic (Canada)	$ —	$ —
Foreign (US)	(19)	17
Total current expense (benefit)	(19)	17
Deferred expense (benefit)		
Domestic (Canada)	—	—
Foreign (US)	—	—
Total deferred tax expense (benefit)	—	—
Total income tax expense (benefit)	$ (19)	$ 17

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:

	Year ended October 31,	
	2024	2023
Income at Canadian statutory rate	26.50 %	26.50 %
Conversion of debentures	—	(21.90)%
State taxes, net of federal benefit	0.18 %	0.05 %
Permanent differences	(2.77)%	1.68 %
Tax credits	1.07 %	0.19 %
Foreign rate differential	(0.17)%	(0.04)%
Valuation allowance	(25.02)%	(6.52)%
Other	0.24 %	0.03 %
	0.03 %	(0.01)%

The net deferred income tax balances related to the following:

	October 31,	
	2024	2023
Deferred tax assets:		
R&D expenditures	8,172	7,012
Net operating loss (NOL) carryforwards	31,661	18,918
Capital loss carryforwards	97	—
Investment tax credits, net	1,934	1,210
Property and equipment	704	791
Financing costs	5,452	2,440
Accruals	747	149
Section 174 capitalized R&D costs	—	393
Operating lease liability	404	—
Note payable	197	—
Other	1	172
Total deferred tax assets	49,369	31,085
Deferred tax liabilities:		
Operating lease-right of use asset	(377)	—
Total deferred tax liabilities	(377)	—
Valuation allowance	(48,992)	(31,085)
Net deferred tax assets (liability)	—	—

The calculation of the Company’s tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the provinces and states in which the Company operates or does business in. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company records uncertain tax positions as liabilities in accordance with ASC 740 and adjusts these liabilities when the Company’s judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of October 31, 2024 and 2023, no uncertain tax positions have been recorded in the consolidated financial statements.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations and comprehensive loss. As of October 31, 2024 and 2023, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.

As of October 31, 2024, the Company has Canadian Federal NOL carryforwards of $119.1 million, that expire between 2026 and 2044 and Canadian provincial NOL carryforwards of $113.1 million, that expire between 2029 and 2044. These losses are available to offset future taxable income in Canada and Quebec. As of October 31, 2024, the Company has a U.S. Federal NOL carryforward of $1.9 million, that may be carried forward indefinitely, and a U.S. state NOL carryforward of $1.4 million, which are available to offset against future taxable income in the U.S and Massachusetts. The U.S. State tax loss carryforward will expire between 2041 and 2043. The Company has not recognized the tax benefit of these losses.

As of October 31, 2024, the Company also has non-refundable Canadian investment tax credits of $2.6 million that expire between 2025 and 2044. These credits may be utilized to reduce Canadian federal income taxes payable. The Company has not recognized the tax benefits related to these non-refundable investment tax credits.

As of October 31, 2024, the Company also has capital losses of $0.7 million which are available to be used indefinitely against future capital gains.

As of October 31, 2023, the Company had SR&ED expenditures of approximately $29.6 million for Canadian federal purposes and $32.5 million for Québec provincial purposes, which have not been deducted. These expenditures are available to reduce future taxable income and have an unlimited carryforward period. SR&ED expenditures are subject to verification by the tax authorities and, accordingly, the amounts may vary.

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Leases	12 Months Ended Oct. 31, 2024

Leases [Abstract]

Leases

16. Leases

The Company’s leases are comprised of all operating leases for office and lab space.

In November 2021, the Company entered into an office and lab space lease approximating 9,360 of rentable square feet for designated office and lab spaces located at 7171 Frederick-Banting, City of Montreal, judicial district of Montreal, Province of Quebec. The lease commenced in November 2021 and had an initial term of 12 months that would have expired on October 31, 2022, and includes options to renew for consecutive twelve-month periods upon landlord consent at new lease rates. As the Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet, this was considered short-term leases, and no operating lease right of use assets and liabilities were recognized. In October 2022, the Company entered into a lease amendment to extend the lease for an additional term of six months through April 2023, with an option to extend the lease through September 2023. In April 2023, the Company extended the lease through September 2023. The lease was further extended through November 5, 2023. The amendment resulted in $0.2 million of additional lease commitments to be paid during the extended term, inclusive of the extension through November 5, 2023.

On December 29, 2022, the Company signed a new lease for approximately 10,620 square feet of new laboratory and office space at 4868 Rue Levy, Montreal, QC. The term of the lease is for 10 years, beginning on the commencement date, and requires an annual initial base rent of $36.50 CAD per square foot, which is subject to annual increases of 2%. The lease did not commence as of October 31, 2023 as the Company did not have access to the space as of that date. The lease commenced in November 2023.

On January 1, 2024, the Company entered into a lease agreement, in which the Company is leasing approximately 6,450 square feet of office space located at 200 Fifth Avenue, Waltham, Massachusetts 02451. The Company will make an aggregate amount of base rental payments of $0.5 million under the initial term of the lease, which is set to expire on December 30, 2026 and does not have an option to renew. Upon commencement, the Company recognized an initial lease liability and corresponding right of use asset of $0.4 million.

During the year ended October 31, 2024 and 2023, the components of operating lease cost were as follows, and are reflected in general and administrative expenses and research and development expenses, as determined by the underlying activities:

	Year Ended October 31,	
	2024	2023
Lease Cost:		
Operating lease cost	444	—
Variable operating lease cost	24	62
Short-term operating lease cost	—	411
Total operating lease cost	468	473

The following table summarizes the cash paid for amounts included in the measurement of the Company’s operating lease liabilities for the year ended October 31, 2024, and 2023:

	Year Ended October 31,	
	2024	2023
Cash paid for amounts included in the measurement of operating lease liabilities	$ 365	$ —

Maturities of the Company's operating lease liabilities as of October 31, 2024 are as follows:

2025	452
2026	464
2027	323
2028	299
2029	305
Thereafter	1,395
Total	3,238
Less: Interest	(1,388)
Total lease liability	1,850

As of October 31, 2024, the Company had operating lease liabilities of $1.8 million recorded on the balance sheet. As of October 31, 2023, there were no operating lease liabilities recorded on the balance sheet.

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Commitments and Contingencies	12 Months Ended Oct. 31, 2024
Commitments and Contingencies Disclosure [Abstract]	
Commitments and Contingencies	

17. Commitments and Contingencies

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of October 31, 2024 and 2023, there were no matters which would have a material impact on the Company’s financial results.

Purchase and Other Obligations

The Company enters into contracts in the normal course of business with CROs, CDMOs and other third-party vendors for nonclinical research studies and testing, clinical trials and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including those incurred by subcontractors of our suppliers.

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Related Party Transactions	12 Months Ended Oct. 31, 2024
Related Party Transactions [Abstract]	
Related Party Transactions	

18. Related Party Transactions

During the year ended October 31, 2024 and 2023, the Company had the following transactions with shareholders that hold more than 10% of the total outstanding shares of the Company:

On February 20, 2024, the Company completed the February 2024 PIPE Financing, which provided for the private placement of 20,000,000 Common Shares, at a price of $10.00 per share and included both new and existing investors. One of the Company’s directors, Mr. Gerald Brunk, is a managing director of Lumira Ventures (“Lumira”), and certain entities affiliated with Lumira were party to the 2024 Subscription Agreements, purchasing an aggregate of 800,000 Common Shares for a total price of $8.0 million in the February 2024 PIPE Financing.

On October 29, 2024, the Company completed the October 2024 PIPE Financing, which provided for the private placement of 6,758,311 Common Shares at a price of $8.90 per share and included both new and existing investors. Two of the Company’s directors, Messrs. Jasper Bos and Wouter Joustra, are general partners of FEAC, and an entity affiliated with FEAC was party to one of the October 2024 Subscription Agreements, purchasing an aggregate of 561,797 Common Shares for a total price of approximately $5.0 million in the October 2024 PIPE Financing.

On April 4, 2023, the Company entered into the April 2023 Notes for a principal amount of $8.0 million with the April 2023 investors, as described in Note 8. The April 2023 Notes had an interest free period of 45 days from the date of issuance, and commencing on the 46th day, is to accrue interest at a rate of 15% per annum. The April 2023 Notes had a maturity date which was the earlier of (i) July 31, 2023; or (ii) the date the Company completes a qualified financing, as defined within the April 2023 Notes as a financing pursuant to which the Company sells convertible promissory notes, warrants, preferred shares, common shares, or a combination thereof of the Company for an aggregate amount of at least $20.0 million. Upon the completion of the 2023 Financing, which met the definition of a qualified financing as defined within the April 2023 Notes, the Company issued and aggregate amount of $8.0 million of convertible debentures and warrants of the Company to the April 2023 Note investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing, for the extinguishment and settlement of the April 2023 Notes.

On May 16, 2023, concurrently with the execution and delivery of the Merger Agreement, the Company entered into agreements pursuant to which it issued new convertible indebtedness and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in settlement and extinguishment of the April 2023 Notes for an aggregate amount of $8.0 million, as described in Note 9, Notes Payable. The 2023 Financing occurred in two separate issuances with $28.0 million issued in May 2023 for $20.0 million in cash and $8.0 million in repayment of the April 2023 Notes, and an additional $10.0 million issued in June 2023 for $10.0 million in cash. The 2023 Notes issued as part of the 2023 Financing have an initial maturity date of three years from the closing date and are to accrue interest at 10% per annum, which is payable upon maturity. The 2023 Notes have the same conversion terms as the 2022 Notes (as described in Note 9, Notes Payable). Of the $38.0 million of convertible debentures and warrants issued, $8.0 million was issued to existing shareholders of the Company, $20.0 million was issued to Forbion Growth Sponsor FEAC I B.V., and $10 million which was issued to Investissement Québec.

On October 31, 2023, upon the consummation of the Reverse Recapitalization, all of the Old enGene’s redeemable convertible preferred shares outstanding immediately prior to the close were exchanged for shares of the Company’s common shares, with no dividends or distributions being declared or paid on Old enGene’s redeemable convertible preferred shares. Further, certain of Old enGene’s existing convertible notes were converted into common shares of Old enGene at the conversion ratio in place at the time of conversion, and all of Old enGene’s common shares were exchanged for common shares of Company at the Exchange Ratio of approximately 0.18048. A total of 13,091,608 common shares of the Company were issued to the Old enGene’s equity and convertible note holders upon the close of the Reverse Recapitalization, of which 2,262,351 were issued to Forbion Growth Sponsor FEAC I B.V, as a result of its’ participation in the 2023 Financing. Each of Old enGene’s outstanding warrants to purchase common shares were exchanged for 2,679,432 common share warrants upon the close of the Reverse Recapitalization of which 950,153 were issued to Forbion Growth Sponsor FEAC I B.V, as a result of its’ participation in the 2023 Financing. All of Old enGene’s existing outstanding Class C Warrants outstanding at the time of the Reverse Recapitalization were terminated. Additionally, there were 3,670,927 common shares of the Company issued to FEAC and its shareholders, as part of the Reverse Recapitalization, along with 5,029,444 warrants to purchase common shares.

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Subsequent Events	12 Months Ended Oct. 31, 2024
Subsequent Events [Abstract]	
Subsequent Events	

19. Subsequent Events

On December 18, 2024 the Company entered into the First Amendment to Amended and Restated Loan and Security Agreement with Hercules (the “First Amendment”), which amended the Amended Loan Agreement dated December 22, 2023. Pursuant to the First Amendment, the $7.5 million advance originally available upon achievement of the Interim Milestone (defined above) was added to the uncommitted tranche subject to the Lenders’ investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time that the Lenders make additional term loan advances to the Company in an aggregate principal amount of up to $27.5 million. The Amended Term Loan Agreement did not change the total term loan facility available to the Company of up to $50.0 million.

The Company has evaluated subsequent events through the date these financial statements were issued. The Company concluded that no additional subsequent events have occurred that require disclosure.

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Summary of Significant Accounting Policies (Policies)	12 Months Ended Oct. 31, 2024
Accounting Policies [Abstract]	
Basis of Presentation	

Basis of Presentation

The accompanying consolidated financial statements are prepared in accordance with U.S. GAAP and include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and as amended by Accounting Standards Updates (“ASU’s”) of the Financial Accounting Standards Board (“FASB”).

The consolidated financial statements are expressed in US dollars. The consolidated financial statements have been prepared on a historical cost basis, except for items that are required to be accounted for at fair value.

As the merger with FEAC has been accounted for as a reverse recapitalization, the historical operations of the Company represent that of Old enGene which is the accounting predecessor. The number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization have been retrospectively restated to reflect the Exchange Ratio of approximately 0.18048 established in the Merger Agreement. Please see Note 3, Reverse Recapitalization for additional information.

Use of Estimates

Use of Estimates

The preparation of the Company’s consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include but are not limited to the accrual of research and development expenses, share-based payments and the recoverability of investment tax credits receivable and, in addition, for fiscal 2023: the valuations of common shares, redeemable convertible preferred shares, warrants to purchase redeemable convertible preferred shares, convertible debentures, and embedded derivatives on convertible debt. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Actual results could differ from those estimates and such differences may be material to the consolidated financial statements.

Segment Information

Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates as a single business segment focused on research, discovery, and clinical development of human genetic medicine products. The majority of the Company’s tangible assets are held in Canada.

Risk of Concentrations of Credit and Off-Balance Sheet Risk

Risk of Concentrations of Credit and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits. Management believes that the Company is not currently exposed to significant credit risk as the Company’s deposits were held in custody at third-party financial institutions.

The Company's investment policy limits investments to certain types of securities issued by the U.S. Government and its agencies, as well as institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of marketable securities to the extent recorded on the Consolidated Balance Sheets. As of October 31, 2024 and 2023, the Company had no off-balance sheet concentrations of credit risk.

The Company is dependent on third-party CDMOs and CRO with whom it does business. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities in its programs. The Company also relies on a limited number of third-party CROs to perform research and development activities on its behalf. These programs could be adversely affected by significant interruption from these providers.

Cash and Cash Equivalents

Cash and Cash Equivalents

The Company considers all short-term, highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company’s cash and cash equivalents include bank balances, demand deposits and other short-term, highly liquid investments. The fair value of cash and cash equivalents approximate the amortized cost. The Company had $173.0 million of cash and cash equivalents as of October 31, 2024 and $81.5 million of cash as of October 31, 2023.

Marketable securities

Marketable securities

The Company's marketable securities are maintained by investment managers and consist of money market funds, U.S. government agency securities and treasuries. If the remaining contractual maturity is within one year from the balance sheet date, the marketable securities are classified as current and otherwise, they are classified as non-current assets.

Investment in marketable securities is classified as available-for-sale and is reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale securities are reported as a separate component of stockholders' equity in other comprehensive loss. Premium or discounts from par value are amortized to investment income over the life of the underlying investment.

The Company periodically evaluates the need for an allowance for credit losses. The evaluation includes consideration of several qualitative and quantitative factors, including whether it has plans to sell the security, whether it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis, and if the entity has the ability and intent to hold the security to maturity, and the portion of any unrealized loss that is the result of a credit loss. Factors considered in making these evaluations include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, expected cash flows from securities, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and the Company's strategy and intentions for holding the marketable security.

When the fair value is below the amortized cost of the asset, an estimate of expected credit losses is made. The Company records credit losses in the consolidated statements of operations and comprehensive loss as a credit loss expense within other income, net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale securities.

Accrued interest receivable related to the Company's available-for-sale securities is presented within prepaids and other current assets on the Company's consolidated balance sheets. The Company has elected the practical expedient available to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivable associated with its marketable securities.

Property and Equipment

Property and Equipment

Property and equipment are comprised mainly of research and development equipment, computer hardware and software, office furniture and equipment, and leasehold improvements. Property and equipment are stated at cost less accumulated depreciation and accumulated impairment losses, if applicable. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Lab equipment	5 years
Computer equipment	3 years
Computer software	5 years
Office furniture	5 years
Leasehold improvements	Shorter of remaining lease term or useful life

Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheet and any resulting gains or losses are included in the consolidated statements of operations and comprehensive loss in the period of disposal.

The Company reviews long-lived assets, such as property and equipment, for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. If indicators of impairment are present, the assets are tested for recoverability by comparing the carrying amount of the assets to the related estimated future undiscounted cash flows that the assets are expected to generate. If the expected undiscounted cash flows are less than the carrying value of the assets, then the assets are considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows. To date, no such impairment losses have been recorded.

Leases

Leases

The Company adopted FASB ASC 842 with an effective date of November 1, 2019, using the modified retrospective transition approach which uses the effective date as the date of initial application. In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use (“ROU”) asset and a lease liability on the consolidated balance sheet for all leases with an initial lease term of greater than 12 months. The Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.

Fair Value Measurements of Financial Instruments

Fair Value Measurements of Financial Instruments

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

At October 31, 2024, financial instruments measured at fair value on a recurring basis include marketable securities (see Note 5, Marketable Securities, and Note 4, Fair Value Measurements). The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term nature.

Fair Value Option

Fair Value Option

The Company elected the fair value option of accounting of ASC 825 for all convertible debentures issued in fiscal 2023 from their issuance date in order to not have to bifurcate any embedded derivatives in accordance with ASC 815. The notes for which the fair value option of accounting is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the notes accounted for at fair value, which include accrued interest, if any, are recorded as a component of other expense (income), net in the consolidated statement of operations and comprehensive loss. The Company has not elected to present interest expense separately from changes in fair value and therefore will not present interest expense associated with the notes. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income. During the year ended October 31, 2023, the Company did not record any changes in fair value related to instrument-specific credit risk. All costs associated with the issuance of the convertible debentures accounted for using the fair value option were expensed upon issuance.

Debt Issuance Costs

Debt Issuance Costs

The Company capitalizes certain legal, accounting, and other third-party fees that are directly associated with the issuance of debt not accounted for using the fair value option as debt issuance costs. Debt issuance costs are recorded as a direct reduction of the carrying amount of the associated debt on the Company’s consolidated balance sheets and amortized as interest expense on the Company’s consolidated statements of operations and comprehensive loss using the effective interest method.

Convertible Debenture Embedded Derivative Liabilities

Convertible Debenture Embedded Derivative Liabilities

The Company’s convertible debentures contained certain features that meet the definition of embedded derivatives requiring bifurcation from the convertible debenture instrument, for which the fair value option was not elected, as a separate compound derivative. The convertible debenture embedded derivative liabilities are initially measured at fair value on issuance and is subject to remeasurement at each reporting period with changes in fair value recognized in the change in fair value of derivative liabilities, net in the consolidated statements of operations and comprehensive loss.

Common Share and Preferred Share Warrants

Common Share and Preferred Share Warrants

The Company accounts for its common share warrants and redeemable convertible preferred shares warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants that have been determined to be classified as liabilities are recorded on the consolidated balance sheets at their fair value on the date of issuance and remeasured to fair value at each reporting period, with the changes in fair value recognized in the change in fair value of warrant liabilities, net in the consolidated statements of operations and comprehensive loss. The Company adjusted the liability for changes in the fair value of these warrants until the earlier of the exercise of the warrants, the expiration of the warrants, or until such time as the warrants were no longer considered liability.

Convertible Debentures

Convertible Debentures

The Company’s 2022 Notes (as defined in Note 9, Notes Payable) are convertible debentures that consist of a debt instrument, a minimum interest obligation, and a share conversion feature. Certain of the convertible debentures issued by the Company also included warrants to purchase redeemable convertible preferred shares, which were classified as liabilities. The Company identified embedded derivatives related to certain share conversion and repayment features within the convertible notes that required bifurcation as a single compound derivative instrument. At inception, the Company utilized the residual method to determine the value of the debt instrument based on the difference between gross proceeds and the estimated fair value of the embedded derivative and any warrants that were issued. The debt instrument is accounted for using the amortized cost method. The discounts on debt resulting from any issuance costs, embedded derivatives and warrants are amortized over the life of the debt using the effective interest method. The issuance costs allocated to the embedded derivatives and warrants are expensed at inception.

Research and Development Expenses

Research and Development Expenses

Research and development expenses are comprised primarily of costs incurred for our drug discovery efforts and development of our product candidates. These expenses include salaries, employee benefits, and share-based compensation expense for our research and development personnel, materials, supplies, depreciation on and maintenance of research equipment, the cost of services provided by outside CROs and consultants to conduct research and development activities including costs of clinical trials and manufacturing, and the allocable portions of facility costs, such as rent, utilities, and general support services. All costs associated with research and development are expensed as incurred.

Management estimates the Company’s accrued research and development expenses as of each balance sheet date in the Company’s financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Patent Costs

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent-related costs are classified as general and administrative expenses within the Company’s consolidated statements of operations.

Share-Based Compensation

Share-Based Compensation

The Company has an incentive equity plan (the “2023 Incentive Equity Plan” or the “2023 Plan”), whereby employees render services as consideration for equity instruments. The 2023 Plan was adopted on October 31, 2023 upon the completion of the Reverse Recapitalization and superseded Old enGene’s employee stock option plan (the “ESOP”) and equity incentive plan (the “EIP”) (collectively, the “Old Plans”). The Company measures all share-based awards granted to employees, officers, directors and non-employees based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures of its share-based awards as they occur. The Company issues share-based awards with service-based vesting conditions and awards with both performance and service-based vesting conditions. For share-based awards with service-based vesting conditions, the Company records the expense using the straight-line method including when such awards have graded vesting. For share-based awards with both performance and service-based vesting conditions, the Company records the expense using an accelerated attribution method, once the performance conditions are considered probable of being achieved, using management’s best estimate.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the Company’s common shares, expected share price volatility, the expected term of the award, the risk-free interest rate for a period that approximates the expected term of the option, and the Company’s expected dividend yield. The Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies with similar characteristics including market capitalization, stage of development, therapeutic focus and certain financial measures. The expected volatility has been determined using an average of the historical volatility measures of this group of guideline companies. The expected option term was calculated based on the simplified method for awards with only service based vesting conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to develop an estimate based on participant behavior. For awards with both performance and service based vesting conditions, the expected term has been determined using management’s best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, if any, and comparison to expected terms used by peers. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common shares; therefore, the expected dividend yield is assumed to be zero.

Prior to the consummation of the Reverse Recapitalization, because there was no public market for the Company’s common shares, the Board of Directors has determined the fair value of the Company’s common shares based on third-party valuations of the Company’s common shares. Initially, the estimated enterprise equity value of the Company was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Company’s various securities of its capital structure using an option pricing method, or OPM, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another.

Significant assumptions used in the OPM to determine the fair value of common shares include volatility, discount for lack of marketability, and the expected timing of a future liquidity event such as an initial public offering (“IPO”), or sale of the Company in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios. In addition, the Company’s Board of Directors considered various objective and subjective factors to determine the fair value of the Company’s common shares as of each grant date, including the prices at which Old enGene sold shares of redeemable convertible preferred shares and the superior rights and preferences of the redeemable convertible preferred shares relative to its common shares at the time of each grant, external market conditions, the progress of the Company’s research and development programs, the Company’s financial position, including cash on hand, and its historical and forecasted performance and operating results, and the lack of an active public market for the Company’s common shares and redeemable convertible preferred shares, among other factors.

The assumptions underlying these valuations represented management’s best estimate, which involved inherent uncertainties and the application of management’s judgment and these valuations are sensitive to changes in the unobservable inputs. As a result, if the Company had used different assumptions or estimates or if there are changes to the unobservable inputs, the fair value of its common shares and share-based compensation expense could have been materially different.

Subsequent to becoming a publicly traded Company upon the consummation of the Reverse Recapitalization, the fair value of common shares underlying equity awards is based on the market price of the Company’s common stock at the date of the grant.

The Company’s share-based compensation expense is recorded in general and administrative and research and development expenses in the Company’s consolidated statements of operations and comprehensive loss.

Income Taxes

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company’s consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on differences between the consolidated financial statement carrying amounts and the tax basis of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in shareholders’ deficit that result from transactions and economic events other than those with shareholders. The Company’s comprehensive loss includes foreign currency translation.

Net Loss Per Share

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common shares. Net loss per share attributable to common shareholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company’s common shares and participating securities. Net loss attributable to common shareholders is allocated first based on dividend rights and then to common and preferred shareholders based on ownership interests on an as-converted basis as if all the earnings for the period had been distributed.

When considering the impact of the convertible equity instruments, diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred shareholders and warrant holders based on dividend rights and then to common and preferred shareholders and warrant holders based on ownership interests. As preferred shares have converted to common shares at the completion of Reverse Recapitalization, the abovementioned policy is only applicable for the year ended October 31, 2023. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, and the potential issuance of common shares upon the conversion of the convertible notes. Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders is generally the same as basic net loss per share attributable to common shareholders because dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. See Note 15, Net Loss per Share, for further detail.

Deferred Transaction Costs

Deferred Transaction Costs

The Company capitalized certain legal, professional accounting and other third-party fees that were directly associated with the Reverse Recapitalization and PIPE Financing as deferred transaction costs until such transaction was consummated. After the consummation of such transaction, these costs were recorded within equity as a reduction of the common share and warrants value within additional paid in capital, for both instruments issued and assumed to shareholders of FEAC and to PIPE financing investors, were allocated to each on a relative fair value basis. The Company incurred a total of $11.3 million of transaction costs as part of the Reverse Recapitalization and PIPE Financing. In addition, transaction costs of $0.8 million related to the issuance of the April 2023 Notes and the May 2023 Notes for which the fair value option of accounting was elected and those allocated to the liability classified warrants issued as part of the 2023 Financing are not deferred and are included in general and administrative expenses in the Company’s consolidated statements of operations and comprehensive loss.

Government Assistance

Programs for Research and Development Expenditures

Government Assistance Programs for Research and Development Expenditures

The Company was eligible to claim Canadian federal and provincial tax credits as a Canadian controlled private corporation (“CCPC”) on eligible scientific research and experimental development (“SR&ED”) expenditures through September 2023, at which time the Company lost its status as a CCPC. In addition, effective for fiscal 2023, the Company’s maximum refundable tax credits were reduced due to the Company’s taxable capital, as defined in the *Income Tax Act* (Canada), which reduction in credits has been recorded in the fourth quarter. The Canadian federal government offers a tax incentive to companies performing research and development activities in Canada and this tax incentive can be refunded or used to reduce federal income taxes in Canada otherwise payable. Such credits, if not refunded or used in the year earned, can be carried forward for a period of twenty years. The Quebec provincial government offers a similar refundable incentive. The investment tax credits recorded are based on management’s estimates of amounts expected to be recovered and are subject to audit by the taxation authorities, the resulting adjustments of which could be significant. Following the loss of CCPC status, the Company’s SR&ED tax credits will be earned at a lower rate and some will no longer be refundable.

Amounts received or receivable resulting from government assistance programs, including investment tax credits for SR&ED, are recognized when there is reasonable assurance that the amount will be received, and all attached conditions will be complied with. Reimbursements of eligible SR&ED expenditures pursuant to government assistance programs are received in cash. The amounts receivable are recorded as reductions of research and development costs when the related costs have been incurred and there is reasonable assurance regarding collection of the claim. During the years ended October 31, 2024 and 2023, the Company recorded $0.4 million and $1.1 million, respectively, as a reduction of research and development expense associated with SR&ED investment tax credits.

Recently Adopted Accounting Pronouncements and Recently Issued Accounting Pronouncements - Not Yet Adopted

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). This new standard changes the impairment model for most financial assets and certain other instruments. Entities will be required to use a model that will result in the earlier recognition of allowances for losses for trade and other receivables, held-to-maturity debt securities, loans, and other instruments. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. In November 2019, the FASB issued ASU 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) (“ASC 2019-10”), which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, for entities meeting the definition of a smaller reporting company. The Company adopted ASU 2016-13 effective November 1, 2023 and the adoption did not have a material impact on the consolidated financial statements.

Recently Issued Accounting Pronouncements – Not Yet Adopted

In June 2022, the FASB issued ASU No. 2022-03, Fair Value Measurement (Topic 820) – Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions, which amends guidance in ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company does not expect that the adoption of this standard will have a material impact on its financial statements and related disclosures.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which requires incremental disclosure of segment information on an interim and annual basis. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application to all prior periods presented in the financial statements is required for public entities. The Company is currently evaluating the impact of the guidance on the financial statements disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires entities to disclose additional information about specific expense categories in the notes to the financial statements. The ASU is effective for annual periods beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is

permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the effect of this update on its consolidated financial statements and related disclosures.

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Summary of Significant Accounting Policies (Tables)	**12 Months Ended**
	Oct. 31, 2024

Accounting Policies [Abstract]

Summary of Estimated Useful Life of Each Asset

Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Lab equipment	5 years
Computer equipment	3 years
Computer software	5 years
Office furniture	5 years
Leasehold improvements	Shorter of remaining lease term or useful life

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Reverse Recapitalization (Tables)	**12 Months Ended**
	Oct. 31, 2024

Stockholders' Equity Note [Abstract]

Summary of Net Proceeds from Reverse Recapitalization and PIPE Financing

The following table summarizes the elements of the net proceeds from the Reverse Recapitalization and PIPE Financing transaction as of October 31, 2023:

	Recapitalization
Cash – FEAC’s Trust Account and Cash (net of redemptions and cash paid for FEAC expenses prior to close)	$ 7,363
Cash – PIPE Financing	56,892
Less transaction costs withheld from cash proceeds on Closing Date	(6,024)
Cash proceeds received from the Reverse Recapitalization and PIPE Financing on Closing Date	$ 58,231
Less transaction costs previously deferred and netted against proceeds	(5,086)
Net cash proceeds from the Reverse Recapitalization and PIPE Financing	53,145

Summary of Number of Common Shares Outstanding

The following table summarizes the number of common shares outstanding immediately following the consummation of the Reverse Recapitalization and PIPE Financing transaction:

	Number of Shares
Old enGene Shareholders (Excluding Convertible Notes)	6,711,786
FEAC Shareholders, including sponsor's and shareholder with non-redemption agreement	3,670,927
Convertible Notes - Common Shares Issued	6,379,822
Common shares issued to PIPE Investors	6,435,441
Total common shares outstanding immediately after the Reverse Recapitalization and PIPE Financing	23,197,976

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Fair Value Measurements (Tables)	**12 Months Ended**
	Oct. 31, 2024

Fair Value, off-Balance-Sheet Risks, Disclosure Information [Line Items]

Schedule of Fair Value Hierarchy for Financial Assets Measured at Fair Value

The following table presents the Company's fair value hierarchy for financial assets measured at fair value as of October 31, 2024:

		October 31, 2024		
Description	**Total**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Other Observable Inputs (Level 3)**
Assets				
Cash equivalents				
Money market funds	121	121	—	—
U.S. government treasuries	94,236	94,236	—	—
Government agency securities	9,955	—	9,955	—
Short term marketable securities:				
U.S. government treasuries	51,574	51,574	—	—
Government agency securities	13,754	—	13,754	—
Long term marketable securities:				
U.S. government treasuries	49,627	49,627	—	—
Government agency securities	9,900	—	9,900	—
Total financial assets	$ 229,167	$ 195,558	$ 33,609	$ —

Convertible Debentures Embedded Derivative Liabilities

Fair Value, off-Balance-Sheet Risks, Disclosure Information [Line Items]

Assumptions Used to Determine Fair Value of Liabilities

The assumptions ranges that the Company used to determine the fair value of the convertible debentures embedded derivative liabilities for the 2022 Notes and BDC Notes that were outstanding as of each respective period (refer to Note 9, Notes Payable) were as follows:

	Immediately prior to settlement on October 31, 2023
Probability of qualified financing*	100 %
Volatility**	n/a
Class C Preferred Share price (CAD)**	n/a
Liquidity price at conversion of listing event***	$ 8.84
Fair value of common share at conversion of listing event***	$ 21.70
Discount rate****	18.4 %
Expected time to respective scenarios	0.0 years

Summary of Change in Estimated Fair Value of Liabilities

The following table provides a summary of the change in the estimated fair value of the Company’s convertible debentures embedded derivative liabilities for the year ended October 31, 2023:

	Total
Balance as of October 31, 2022	3,791
Change in fair value of convertible debenture embedded derivative liabilities	21,421
Foreign exchange rate translation adjustment	5
Settlement of derivative liability in accordance with repayment and conversion of convertible debentures upon the consummation of the Reverse Recapitalization	(25,217)
Balance as of October 31, 2023	$ —

May 2023 Notes

Fair Value, off-Balance-Sheet Risks, Disclosure Information [Line Items]

Assumptions Used to Determine Fair Value of Liabilities

The assumptions that the Company used to determine the fair value of the May 2023 Notes as of the issuance date are as follows:

	As of Issuance Date
Probability of qualified financing*	60 %
Volatility	85 %
Class C Preferred Share Price (CAD)	$ 2.074
Liquidity price at conversion of listing event**	$ 8.42
Fair value of common share at conversion of listing event**	$ 10.25
Discount rate***	40.8 %
Expected time to respective scenarios	0.3 years

Summary of Change in Estimated Fair Value of Liabilities

The following table provides a summary of the change in the estimated fair value of the Company’s 2023 Notes for the year ended October 31, 2023. Upon the close of the Reverse Recapitalization the 2023 Notes were exchanged for common shares of the Company, resulting in an extinguishment of the 2023 Notes. See Note 3, Reverse Recapitalization and Note 10, Convertible Debentures.

	Total
Balance as of October 31, 2022	$ —
Issuance of May 2023 Notes	37,043
Change in fair value of May 2023 Notes	56,212
Settlement of 2023 Notes upon the consummation of the Reverse Recapitalization	(93,255)
Balance as of October 31, 2023	$ —

Preferred Share Warrant Liabilities

Fair Value, off-Balance-Sheet Risks, Disclosure Information [Line Items]

Summary of Change in Estimated Fair Value of Liabilities

The following table provides a summary of the change in the estimated fair value of the Company’s warrant liabilities for the year ended October 31, 2023:

	Total
Balance as of October 31, 2022	11,456
Warrant liability recognized upon issuance of May 2023 Notes	1,420
Change in fair value of warrant liabilities	(10,849)
Foreign exchange rate translation adjustment	(44)
Reclassification of 2023 Warrants to equity upon consummation of the Reverse Recapitalization	(1,983)
Balance as of October 31, 2023	$ —

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Marketable securities (Tables)

12 Months Ended Oct. 31, 2024

Investments, Debt and Equity Securities [Abstract]

Schedule of Marketable Securities

As of October 31, 2024, the marketable securities consisted of the following:

	October 31, 2024			
Description	Amortized Cost	Unrealized Holdings Gains	Unrealized Holdings Losses	Aggregate Fair Value
Cash equivalents and short-term investments:				
Money market funds, included in cash and cash equivalents	$ 121	$ —	$ —	$ 121
US treasury	145,832	12	(30)	145,814
Government agency securities	23,714	3	(8)	23,709
Total cash equivalents and short-term investments	$ 169,667	$ 15	$ (38)	$ 169,644
Long-term investments				
US treasury	49,931	—	(306)	49,625
Government agency securities	9,972	—	(74)	9,898
Total long-term investments	$ 59,903	$ —	$ (380)	$ 59,523
Total	$ 229,570	$ 15	$ (418)	$ 229,167

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Property and Equipment, Net (Tables)

12 Months Ended Oct. 31, 2024

Property, Plant and Equipment [Abstract]

Summary of Property and Equipment

As of October 31, 2024 and 2023, property and equipment, consisted of the following:

	October 31, 2024	October 31, 2023
Lab equipment	$ 2,191	$ 1,779
Computer equipment	62	269
Computer software	146	70
Office furniture	141	69
Leasehold improvements	239	129
Property and equipment	2,779	2,316
Less: Accumulated depreciation and amortization	1,610	1,727
Property and equipment, net	$ 1,169	$ 589

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Accrued Expenses and Other Current Liabilities (Tables)

12 Months Ended Oct. 31, 2024

Payables and Accruals [Abstract]

Summary of Accrued Expenses and Other Current Liabilities

As of October 31, 2024 and 2023, accrued expenses and other current liabilities consisted of the following:

	October 31, 2024	October 31, 2023
Accrued research and development expenses	$ 3,773	$ 759
Employee compensation and related benefits	3,475	814
Accrued financing costs (1)	3,831	613
Professional fees	824	1,201

Accrued income taxes payable	-	39
Other	225	113
Total accrued expenses and other current liabilities	$ 12,128	$ 3,539

(1) The presentation of accrued financing costs as of October 31, 2023 has been updated to conform with presentation as of October 31, 2024.

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Notes Payable (Tables)

12 Months Ended Oct. 31, 2024

Debt Disclosure [Abstract]

Schedule of Carrying Value of Term Loan

As of October 31, 2024 and 2023, the carrying value of the Term Loan consists of the following:

	October 31, 2024	October 31, 2023
Note payable, including End of Term Charge	$ 24,663	$ 10,144
Debt discount, net of accretion	(1,673)	(474)
Accrued interest	182	108
Note payable, net of discount	$ 23,172	$ 9,778

Schedule of Estimated Future Principal Payments Due Under the Loan Agreement

stimated future principal payments due under the Loan Agreement, including the contractual End of Term Charge, are as follows:

	Note Principal Payments
2025	$ 699
2026	8,417
2027	10,987
2028	5,161
Total principal payments, including End of Term Charge	25,264

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Common Shares (Tables)

12 Months Ended Oct. 31, 2024

Equity [Abstract]

Schedule of Shares Reserved for Future Issuance Under the Plan

	October 31, 2024	October 31, 2023
Warrants to purchase common shares	8,511,968	10,411,641
Options to purchase common shares	6,034,512	2,706,941
Remaining shares reserved for future issuance under the equity plans	2,752,889	2,607,943
Total	17,299,369	15,726,525

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Share-Based Compensation (Tables)

12 Months Ended Oct. 31, 2024

Share-Based Payment Arrangement [Abstract]

Schedule of Assumptions Used to Determine Grant-Date Fair Value of Stock Options

The assumptions that the Company used to determine the grant-date fair value of stock options during the years ended October 31, 2024 and 2023, were as follows:

	Year ended October 31,	
	2024	2023
Expected term (in years)	5.51-6.08	5.2 – 6.08
Expected volatility	78.24-82.33%	79.92 – 81.48%
Risk-free interest rate	1.78-4.66%	3.56 – 4.35%
Expected dividend yield	—	—
Fair value of common shares and exercise price of options (CAD)	$ N/A	$ 2.11 – 12.36
Fair value of common shares and exercise price of options (USD)	$ 4.73-12.60	$ 1.52 – 8.93

Summary of Stock Option Activity

The following table summarizes the Company’s stock option activity:

	Number of Shares	Weighted-Average Exercise Price (USD)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of October 31, 2023	2,706,941	$ 2.40	8.1	$ 52,192
Granted	3,591,200	10.18		
Exercised	(116,752)	0.97		
Forfeited or expired	(146,877)	6.71		
Outstanding as of October 31, 2024	6,034,512	$ 6.88	7.4	$ 17,809
Options vested and exercisable as of October 31, 2024	2,497,082	$ 2.32	4.4	$ 16,311
Options unvested as of October 31, 2024	3,537,430	$ 10.10	9.6	$ 1,498

Summary of Share-based Compensation Expense

Share-based compensation expense included in the Company’s consolidated statements of operations and comprehensive loss was as follows:

	Year Ended October 31,	
	2024	2023
Research and development	$ 1,794	$ 780
General and administrative	3,530	2,670
Total share-based compensation expense	$ 5,324	$ 3,450

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Net Loss Per Share (Tables)

12 Months Ended Oct. 31, 2024

Earnings Per Share [Abstract]

Summary of Basic and Diluted Net Loss Per Share

The following table sets forth the computation of the Company’s basic and diluted net loss per share for the periods presented, retrospectively restated to reflect the exchange of shares upon the close of the Reverse Recapitalization:

	Year Ended October 31,	
	2024	2023
Numerator:		
Net loss	$ 55,142	$ 99,917
Deemed dividend attributable to redeemable convertible preferred shareholders	—	4,822
Net loss attributable to common shareholders, basic and diluted	$ 55,142	$ 104,739
Denominator:		
Weighted-average number of common shares used in net loss per share, basic and diluted	37,782,346	692,609
Net loss per common share, basic and diluted	$ 1.46	$ 151.22

Summary of Shares Excluded from Computation of Diluted Net Loss Per Share

The Company excluded the following shares from the computation of diluted net loss per share attributable to common shareholders during the year ended October 31, 2024, and 2023 because including them would have had an anti-dilutive effect:

	Year Ended October 31,	
	2024	2023
Warrants to purchase common shares	8,511,968	10,411,641
Options to purchase common shares	6,034,512	2,706,941
Total	14,546,480	13,118,582

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Income Taxes (Tables)

12 Months Ended Oct. 31, 2024

Income Tax Disclosure [Abstract]

Summary of Loss Before Provision for Income Taxes

Loss before provision for income taxes consisted of the following:

Year ended October 31,	
2024	2023

Domestic (Canada)	$ (53,460)	$ (99,157)
Foreign (US)	(1,701)	(743)
Loss before income taxes	$ (55,161)	$ (99,900)

Summary Of Components Of The Provision For (Recovery Of) Income Taxes

The components of the provision for (recovery of) income taxes is as follows:

	Year ended October 31, 2024	Year ended October 31, 2023
Current expense (benefit):		
Domestic (Canada)	$ —	$ —
Foreign (US)	(19)	17
Total current expense (benefit)	(19)	17
Deferred expense (benefit)		
Domestic (Canada)	—	—
Foreign (US)	—	—
Total deferred tax expense (benefit)	—	—
Total income tax expense (benefit)	$ (19)	$ 17

Summary Of Reconciliation Of Company's Statutory Income Tax Rate

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows:

	Year ended October 31, 2024	Year ended October 31, 2023
Income at Canadian statutory rate	26.50 %	26.50 %
Conversion of debentures	—	(21.90)%
State taxes, net of federal benefit	0.18 %	0.05 %
Permanent differences	(2.77)%	1.68 %
Tax credits	1.07 %	0.19 %
Foreign rate differential	(0.17)%	(0.04)%
Valuation allowance	(25.02)%	(6.52)%
Other	0.24 %	0.03 %
	0.03 %	(0.01)%

Summary Of Net Deferred Income Tax

The net deferred income tax balances related to the following:

	October 31, 2024	October 31, 2023
Deferred tax assets:		
R&D expenditures	8,172	7,012
Net operating loss (NOL) carryforwards	31,661	18,918
Capital loss carryforwards	97	—
Investment tax credits, net	1,934	1,210
Property and equipment	704	791
Financing costs	5,452	2,440
Accruals	747	149
Section 174 capitalized R&D costs	—	393
Operating lease liability	404	—
Note payable	197	—
Other	1	172
Total deferred tax assets	49,369	31,085
Deferred tax liabilities:		
Operating lease-right of use asset	(377)	—
Total deferred tax liabilities	(377)	—
Valuation allowance	(48,992)	(31,085)
Net deferred tax assets (liability)	—	—

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Leases (Tables)	**12 Months Ended Oct. 31, 2024**
Lessee Disclosure [Abstract]	
Schedule of Components of Operating Lease Cost	During the year ended October 31, 2024 and 2023, the components of operating lease cost were as follows, and are reflected in general and administrative expenses and research and development expenses, as determined by the underlying activities:

	Year Ended October 31, 2024	Year Ended October 31, 2023
Lease Cost:		
Operating lease cost	444	—
Variable operating lease cost	24	62
Short-term operating lease cost	—	411
Total operating lease cost	468	473

Summary of Cash Paid for Amounts Included in the Measurement of the Operating Lease Liabilities

The following table summarizes the cash paid for amounts included in the measurement of the Company’s operating lease liabilities for the year ended October 31, 2024, and 2023:

	Year Ended October 31, 2024	Year Ended October 31, 2023
Cash paid for amounts included in the measurement of operating lease liabilities	$ 365	$ —

Schedule of Maturities of Operating Lease Liabilities

Maturities of the Company's operating lease liabilities as of October 31, 2024 are as follows:

2025	452
2026	464
2027	323
2028	299
2029	305
Thereafter	1,395
Total	3,238
Less: Interest	(1,388)
Total lease liability	1,850

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Description of Business - Additional Information (Details) - USD ($)		**12 Months Ended**	
	May 16, 2023	**Oct. 31, 2024**	**Oct. 31, 2023**
Description of Business [Line Items]			
Exchange ratio		0.18048%	0.18048%
Net Income (Loss)		$ (55,142,000)	$ (99,917,000)
Cash flows from operating activities		48,281,000	24,743,000
Accumulated deficit		$ 254,730,000	$ 199,588,000
FEAC [Member]			
Description of Business [Line Items]			
Goodwill	$ 0		
Intangible assets	$ 0		
Exchange ratio	0.18048%		

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Summary of Significant Accounting Policies - Additional Information (Detail) - USD ($)	**12 Months Ended**	
	Oct. 31, 2024	**Oct. 31, 2023**
Summary of Significant Accounting Policies [Line Items]		
Exchange ratio	0.18048%	0.18048%
Off-balance sheet concentrations of credit risk description	As of October 31, 2024 and 2023, the Company had no off-balance sheet concentrations of credit risk	
Off-balance sheet concentrations of credit risk	$ 0	$ 0
Cash and cash equivalents	173,004,000	81,521,000
Cash		81,500,000
Restricted investments	$ 72,000	76,000

Percentage of tax benefit to be realized for recognition in the income statement	50.00%	
Transaction costs as part of reverse recapitalization and pipe financing	$ 11,300,000	
Transaction costs related to issuance of notes	800,000	
Research and development investment tax credits	$ 400,000	$ 1,100,000
ASU 2016-13		
Summary of Significant Accounting Policies [Line Items]		
Change in Accounting Principle, Accounting Standards Update, Adopted	true	
Change in Accounting Principle, Accounting Standards Update, Adoption Date	Nov. 01, 2023	
Change in Accounting Principle, Accounting Standards Update, Immaterial Effect	true	

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Summary of Significant Accounting Policies - Summary of Estimated Useful Life of Each Asset (Details)	12 Months Ended
	Oct. 31, 2024
Lab equipment	
Property, Plant and Equipment [Line Items]	
Estimated Useful Life	5 years
Computer Equipment	
Property, Plant and Equipment [Line Items]	
Estimated Useful Life	3 years
Computer Software	
Property, Plant and Equipment [Line Items]	
Estimated Useful Life	5 years
Office Furniture	
Property, Plant and Equipment [Line Items]	
Estimated Useful Life	5 years
Leasehold Improvements	
Property, Plant and Equipment [Line Items]	
Estimated Useful Life	Shorter of remaining lease term or useful life

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Reverse Recapitalization - Additional Information (Details) - USD ($) $ in Thousands	12 Months Ended			
	Oct. 31, 2023	Oct. 31, 2024	Oct. 31, 2023	Jun. 30, 2021
Equity, Class of Treasury Stock [Line Items]				
Common stock shares outstanding	23,197,976	50,976,676	23,197,976	
Warrants outstanding	10,411,641	8,511,968	10,411,641	10,242,130
Common stock shares issued	23,197,976	50,976,676	23,197,976	
Proceeds from trust account			$ 7,363	
Proceeds from PIPE financing			56,892	
Transactions costs deferred and netted against proceeds			$ (5,086)	
FEAC				
Equity, Class of Treasury Stock [Line Items]				
Common stock shares outstanding	3,670,927		3,670,927	
Warrants outstanding	5,029,444	8,449,555	5,029,444	
Proceeds from trust account			$ 7,400	
Merger Agreement [Member]				
Equity, Class of Treasury Stock [Line Items]				
Business combination reverse recapitalization description		On October 31, 2023 (the “Closing Date”), FEAC, Old enGene, and the Company consummated the merger pursuant to the Merger Agreement, dated as of May 16, 2023. As a result of the Reverse Recapitalization, the Company became a publicly traded company, with old enGene, a subsidiary of the Company, continuing the existing business operations.		
Merger agreement date	May 16, 2023			
PIPE Financing				
Equity, Class of Treasury Stock [Line Items]				
Common stock shares outstanding	23,197,976		23,197,976	
Warrants outstanding	10,411,641		10,411,641	
Value of stock and warrant issued during the period			$ 56,900	
Transaction costs	$ 11,100		11,100	
Transactions costs deferred and netted against proceeds			5,100	
PIPE Financing | FEAC				
Equity, Class of Treasury Stock [Line Items]				
Value of stock and warrant issued during the period			$ 56,900	
Number of new stock issued during the period			6,435,441	
Number of new warrant issued during the period			2,702,791	
Common stock, value issued			$ 56,100	
Warrants issued during period, value			800	
Proceeds from PIPE				

financing			56,900
Transaction costs withheld from proceeds received			$ 6,000
Old enGenes Equity and Convertible Note			
Equity, Class of Treasury Stock [Line Items]			
Common stock shares issued	13,091,608		13,091,608
Old enGenes Warrant			
Equity, Class of Treasury Stock [Line Items]			
Share warrants issued	2,679,432		2,679,432
Old enGenes Share Option			
Equity, Class of Treasury Stock [Line Items]			
Common stock shares issued		2,706,941	
Common share options issued	2,706,941		2,706,941

~~***XML 73 R47.htm IDEA: XBRL DOCUMENT***~~

Reverse Recapitalization - Summary of Net Proceeds from Reverse Recapitalization and PIPE Financing (Details) $ in Thousands	12 Months Ended Oct. 31, 2023 USD ($)
Stockholders' Equity Note [Abstract]	
Cash - FEAC's Trust Account and Cash (net of redemptions and cash paid for FEAC expenses prior to close)	$ 7,363
Cash - PIPE Financing	56,892
Less transaction costs withheld from cash proceeds on Closing Date	(6,024)
Cash proceeds received from the Reverse Recapitalization and PIPE Financing on Closing Date	58,231
Less transaction costs previously deferred and netted against proceeds	(5,086)
Net cash proceeds from the Reverse Recapitalization and PIPE Financing	$ 53,145

~~***XML 74 R48.htm IDEA: XBRL DOCUMENT***~~

Reverse Recapitalization - Summary of Number of Common Shares Outstanding (Details)	Oct. 31, 2023 shares
Reverse Recapitalization [Line Items]	
Total Common Shares outstanding immediately after the Reverse Recapitalization and PIPE Financing	23,197,976
Old enGene Shareholders (Excluding Convertible Notes)	
Reverse Recapitalization [Line Items]	
Total Common Shares outstanding immediately after the Reverse Recapitalization and PIPE Financing	6,711,786
FEAC Shareholders, including sponsor's and shareholder with non-redemption agreement	
Reverse Recapitalization [Line Items]	
Total Common Shares outstanding immediately after the Reverse Recapitalization and PIPE Financing	3,670,927
Convertible Notes - Common Shares Issued	
Reverse Recapitalization [Line Items]	
Total Common Shares outstanding immediately after the Reverse Recapitalization and PIPE Financing	6,379,822
Common Shares Issued to Pipe Investors	
Reverse Recapitalization [Line Items]	
Total Common Shares outstanding immediately after the Reverse Recapitalization and PIPE Financing	6,435,441

~~***XML 75 R49.htm IDEA: XBRL DOCUMENT***~~

Fair Value Measurements - Additional Information (Details)			2 Months Ended	12 Months Ended	
	Oct. 31, 2023 USD ($) shares	May 15, 2023 $ / shares	May 31, 2023 $ / shares	Oct. 31, 2024 USD ($) $ / shares	Oct. 31, 2023 USD ($)
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]					
Assets transfers or reclassifications into level 3				$ 0	$ 0
Assets transfers or reclassifications out of level 3				0	0
Liabilities transfers or reclassifications into level 3				0	0
Liabilities transfers or reclassifications out of level 3				$ 0	0
Proceeds from convertible debt					38,000,000
Fair value of shares | $ / shares				$ 18	
Quoted market price of public warrants | $ / shares		$ 0.74	$ 0.53		
Preferred Share Warrants					
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]					
Warrants, contractual term				10 years	
May 2023 Notes					
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]					
Fair value of debt instrument	$ 93,300,000				93,300,000
May 2023 Notes | Common Shares					
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]					
Shares issued in exchange of debt instrument | shares	4,298,463				
2022 Notes and BDC Notes					
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]					
Reverse recapitalization embedded derivative fair value of embedded derivative	$ 24,800,000				24,800,000
Embedded Derivative, Fair Value of Embedded Derivative Liability	$ 400,000				400,000
April 2023 Notes					
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]					
Proceeds from convertible debt					$ 8,000,000
Repayments of convertible notes and warrants				$ 8,000,000	
Measurement Input, Expected Term | 2022 Notes and BDC Notes					
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]					
Embedded derivative liability measurement term	0 years				0 years
Fair Value of Common Share | May 2023 Notes					
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]					
Fair value debt inputs measurement input	0.217				0.217
Fair Value of Common Share | 2022 Notes and BDC Notes					
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]					
Fair value debt inputs measurement input	0.0217				0.0217

Fair Value Measurement Recurring			
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]			
Financial assets, fair value	$ 0	$ 229,167,000	$ 0
Financial liabilities, fair value	$ 0		$ 0

~~***XML 76 R50.htm IDEA: XBRL DOCUMENT***~~

Fair Value Measurements - Schedule of Fair Value Hierarchy for Financial Assets Measured at Fair Value (Details) - Fair Value Measurement Recurring - USD ($)	Oct. 31, 2024	Oct. 31, 2023
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Total financial assets	$ 229,167,000	$ 0
Money Market Funds		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Cash equivalents	121,000	
U.S. Government Treasuries		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Cash equivalents	94,236,000	
Government Agency Securities		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Cash equivalents	9,955,000	
Short Term Marketable Securities | U.S. Government Treasuries		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Marketable securities	51,574,000	
Short Term Marketable Securities | Government Agency Securities		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Marketable securities	13,754,000	
Long Term Marketable Securities | U.S. Government Treasuries		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Marketable securities	49,627,000	
Long Term Marketable Securities | Government Agency Securities		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Marketable securities	9,900,000	
Level 1		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Total financial assets	195,558,000	
Level 1 | Money Market Funds		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Cash equivalents	121,000	
Level 1 | U.S. Government Treasuries		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Cash equivalents	94,236,000	
Level 1 | Short Term Marketable Securities | U.S. Government Treasuries		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Marketable securities	51,574,000	
Level 1 | Long Term Marketable Securities | U.S. Government Treasuries		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Marketable securities	49,627,000	
Level 2		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Total financial assets	33,609,000	
Level 2 | Government Agency Securities		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Cash equivalents	9,955,000	
Level 2 | Short Term Marketable Securities | Government Agency Securities		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Marketable securities	13,754,000	
Level 2 | Long Term Marketable Securities | Government Agency Securities		
Fair Value, Assets and Liabilities Measured on Recurring and Nonrecurring Basis [Line Items]		
Marketable securities	$ 9,900,000	

~~***XML 77 R51.htm IDEA: XBRL DOCUMENT***~~

Fair Value Measurements - Schedule of Convertible Debentures Embedded Derivative Liabilities (Details)	Oct. 31, 2023	May 16, 2023
Probability of Qualified Financing | 2022 Notes and BDC Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input	1	
Probability of Qualified Financing | May 2023 Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input		0.60
Volatility | May 2023 Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input		0.85
Class C Preferred Share Price (CAD) | May 2023 Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input		0.02074
Liquidity price at conversion of listing event | 2022 Notes and BDC Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input	0.00884	
Liquidity price at conversion of listing event | May 2023 Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input		0.00842
Fair value of common share at conversion of listing event | 2022 Notes and BDC Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input	0.0217	
Fair value of common share at conversion of listing event | May 2023 Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input		0.01025
Discount rate | 2022 Notes and BDC Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input	0.0184	

Discount rate | May 2023 Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs measurement input		0.0408
Expected time to respective scenarios | 2022 Notes and BDC Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs, term	0 years	
Expected time to respective scenarios | May 2023 Notes		
Fair Value Measurement Inputs and Valuation Techniques [Line Items]		
Fair value debt inputs, term		3 months 18 days

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Fair Value Measurements - Summary of Change in Estimated Fair Value of Convertible Debentures Embedded Derivative Liabilities (Details) - USD ($) $ in Thousands	12 Months Ended	
	Oct. 31, 2023	Oct. 31, 2022
Fair Value, Net Derivative Asset (Liability) Measured on Recurring Basis, Unobservable Input Reconciliation [Line Items]		
Fair Value, Net Derivative Asset (Liability), Recurring Basis, Unobservable Input Reconciliation, Gain (Loss), Statement of Income or Comprehensive Income [Extensible Enumeration]	Change In Fair Value Of Convertible Debentures Embedded Derivative Liabilities	Change In Fair Value Of Convertible Debentures Embedded Derivative Liabilities
2022 Notes and BDC Notes		
Fair Value, Net Derivative Asset (Liability) Measured on Recurring Basis, Unobservable Input Reconciliation [Line Items]		
Balance	$ 3,791	
Change in fair value of convertible debenture embedded derivative liabilities	21,421	
Foreign exchange rate translation adjustment	5	
Settlement of derivative liability in accordance with repayment and conversion of convertible debentures upon the consummation of the Reverse Recapitalization	$ (25,217)	
Balance		$ 3,791

~~XML 79 R53.htm IDEA: XBRL DOCUMENT~~

Fair Value Measurements - Summary of Change in Estimated Fair Value of Debt Instrument (Details) - May 2023 Notes $ in Thousands	12 Months Ended
	Oct. 31, 2023 USD ($)
Fair Value, off-Balance-Sheet Risks, Disclosure Information [Line Items]	
Issuance	$ 37,043
Change in fair value	56,212
Settlement upon the consummation of the Reverse Recapitalization	$ (93,255)

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Fair Value Measurements - Summary of Change in Estimated Fair Value of Warrant Liabilities (Details)	12 Months Ended
	Oct. 31, 2023 USD ($)
Fair Value, Liabilities Measured on Recurring Basis, Unobservable Input Reconciliation [Line Items]	
Beginning Balance	$ 11,456
Change in fair value of warrant liabilities	(10,849)
Foreign exchange rate translation adjustment	(44)
2023 Warrants	
Fair Value, Liabilities Measured on Recurring Basis, Unobservable Input Reconciliation [Line Items]	
Reclassification of Warrants to equity upon consummation of the Reverse Recapitalization	(1,983)
May 2023 Notes	
Fair Value, Liabilities Measured on Recurring Basis, Unobservable Input Reconciliation [Line Items]	
Warrant liabilities recognized upon issuance	$ 1,420

~~XML 81 R55.htm IDEA: XBRL DOCUMENT~~

Marketable securities - Schedule of Marketable Securities (Details)	Oct. 31, 2024 USD ($)
Marketable Securities [Line Items]	
Amortized Cost	$ 229,570
Unrealized Holdings Gains	15
Unrealized Holdings Losses	(418)
Aggregate Fair Value	229,167
Cash Equivalents and Short-term Investments	
Marketable Securities [Line Items]	
Amortized Cost	169,667
Unrealized Holdings Gains	15
Unrealized Holdings Losses	(38)
Aggregate Fair Value	169,644
Cash Equivalents and Short-term Investments | Money Market Funds	
Marketable Securities [Line Items]	
Amortized Cost	121
Aggregate Fair Value	121
Cash Equivalents and Short-term Investments | US Treasury	
Marketable Securities [Line Items]	
Amortized Cost	145,832
Unrealized Holdings Gains	12
Unrealized Holdings Losses	(30)
Aggregate Fair Value	145,814
Cash Equivalents and Short-term Investments | Government Agency Securities	
Marketable Securities [Line Items]	
Amortized Cost	23,714
Unrealized Holdings Gains	3
Unrealized Holdings Losses	(8)
Aggregate Fair Value	23,709
Long-term Investments	
Marketable Securities [Line Items]	
Amortized Cost	59,903
Unrealized Holdings Losses	(380)
Aggregate Fair Value	59,523
Long-term Investments | US Treasury	
Marketable Securities [Line Items]	

Amortized Cost	49,931
Unrealized Holdings Losses	(306)
Aggregate Fair Value	49,625
Long-term Investments | Government Agency Securities	
Marketable Securities [Line Items]	
Amortized Cost	9,972
Unrealized Holdings Losses	(74)
Aggregate Fair Value	$ 9,898

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Marketable securities - Additional Information (Details)	12 Months Ended	
	Oct. 31, 2024 USD ($) Security	Oct. 31, 2023 USD ($)
Marketable Securities [Line Items]		
Number of securities held | Security	31	
Number of unrealized loss position | Security	21	
Accrued interest receivable	$ 700,000	$ 0
Debt Securities, Available-for-Sale, Accrued Interest, after Allowance for Credit Loss, Statement of Financial Position [Extensible Enumeration]	Prepaid Expense and Other Assets, Current	
Accrued interest receivable written off	$ 0	0
Realized gains or losses on sale or maturity of available-for-sale securities	$ 0	$ 0
US Treasury and Government [Member] | Minimum [Member]		
Marketable Securities [Line Items]		
Debt securities unrealized losses	0.00%	
US Treasury and Government [Member] | Maximum [Member]		
Marketable Securities [Line Items]		
Debt securities unrealized losses	1.00%	

~~XML 83 R57.htm IDEA: XBRL DOCUMENT~~

Property and Equipment, Net - Summary of Property and Equipment (Details) - USD ($) $ in Thousands	Oct. 31, 2024	Oct. 31, 2023
Property, Plant and Equipment [Line Items]		
Property and equipment	$ 2,779	$ 2,316
Less: Accumulated depreciation and amortization	1,610	1,727
Property and equipment, net	1,169	589
Lab Equipment		
Property, Plant and Equipment [Line Items]		
Property and equipment	2,191	1,779
Computer Equipment		
Property, Plant and Equipment [Line Items]		
Property and equipment	62	269
Computer Software		
Property, Plant and Equipment [Line Items]		
Property and equipment	146	70
Office Furniture		
Property, Plant and Equipment [Line Items]		
Property and equipment	141	69
Leasehold Improvements		
Property, Plant and Equipment [Line Items]		
Property and equipment	$ 239	$ 129

~~XML 84 R58.htm IDEA: XBRL DOCUMENT~~

Property and Equipment, Net - Additional Information (Details) - USD ($) $ in Millions	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Property, Plant and Equipment [Abstract]		
Depreciation and amortization expense	$ 0.3	$ 0.2

~~XML 85 R59.htm IDEA: XBRL DOCUMENT~~

Accrued Expenses and Other Current Liabilities - Summary of Accrued Expenses and Other Current Liabilities (Details) - USD ($) $ in Thousands		Oct. 31, 2024	Oct. 31, 2023
Payables and Accruals [Abstract]			
Accrued research and development expenses		$ 3,773	$ 759
Employee compensation and related benefits		3,475	814
Accrued financing costs	[1]	3,831	613
Professional fees		824	1,201
Accrued income tax payable			39
Other		225	113
Total accrued expenses and other current liabilities		$ 12,128	$ 3,539

[1] (1) The presentation of accrued financing costs as of October 31, 2023 has been updated to conform with presentation as of October 31, 2024.

~~XML 86 R60.htm IDEA: XBRL DOCUMENT~~

License Agreement and Clinical Research Organization - Additional Information (Details) - USD ($) $ in Thousands		12 Months Ended	
	Apr. 10, 2020	Oct. 31, 2024	Oct. 31, 2023
License Agreement and Clinical Research Organization [Line Items]			
Annual maintenance fee	$ 50		
Payment to NTC upon assigning the License Agreement	50		
Phase I Clinical Trial [Member]			
License Agreement and Clinical Research Organization [Line Items]			
One-time payment for milestone product	50		
Phase II Clinical Trial [Member]			
License Agreement and Clinical Research Organization [Line Items]			
One-time payment for milestone product	450		
Research and Development			
License Agreement and Clinical Research Organization [Line Items]			
Upfront fee	$ 50		

Expenses related to the annual maintenance fee $ 50 $ 50

~~***XML 87 R61.htm IDEA: XBRL DOCUMENT***~~

Notes Payable - Additional Information (Details)						3 Months Ended	12 Months Ended				
	Oct. 31, 2024 USD ($) $ / shares shares	Dec. 22, 2023 USD ($) $ / shares shares	Apr. 04, 2023 USD ($)	Jun. 15, 2022 USD ($)	Dec. 30, 2021 USD ($)	Apr. 30, 2023 USD ($)	Oct. 31, 2024 USD ($) $ / shares shares	Oct. 31, 2023 USD ($)	Oct. 31, 2024 $ / shares shares	Dec. 15, 2022 USD ($)	Jun. 30, 2022 USD ($) shares
Debt Instrument [Line Items]											
Loss on extinguishment of debt							$ (366,000)				
Note payable current	$ 699,000						$ 699,000	$ 562,000			
Warrants, exercise price per share | $ / shares	$ 11.5						$ 11.5				
Old Hercules Warrants											
Debt Instrument [Line Items]											
Warrants exercisable period	10 years						10 years				
Warrants, exercise price per share | $ / shares									$ 2.632		
Loan and Security Agreement | Old Hercules Warrants											
Debt Instrument [Line Items]											
Exercise price equal to percentage of aggregate amount of term loans							2.50%				
Loan and Security Agreement | Old Hercules Warrants | Class C Preferred Shares											
Debt Instrument [Line Items]											
Warrant issued to purchase preferred shares | shares	84,714						84,714				48,978
Preferred share warrants fair value	$ 34,000						$ 34,000				$ 23,000
Amended Loan Agreement											
Debt Instrument [Line Items]											
Warrant issued to purchase preferred shares | shares		138,696									
Warrants, exercise price per share | $ / shares		$ 7.21									
Percentage of aggregate principal amount of term loan advance to purchase number of common shares		2.00%									
Warrants exercisable period		7 years									
Hercules Capital | Amended Loan Agreement											
Debt Instrument [Line Items]											
Interest expense							2,200,000	1,800,000			
Amortization of debt discount							600,000	$ 400,000			
Borrowed amount	22,500,000						22,500,000				
Debt discount and issuance costs	$ 2,200,000						2,200,000				
Term Loan | Amended Loan Agreement											
Debt Instrument [Line Items]											
Percentage of prepayment premium of principal amount outstanding of the closing date		3.00%									
Percentage of prepayment premium of principal amount outstanding prior to twenty-four months		2.00%									
Percentage of prepayment premium of principal amount outstanding prior to maturity date		1.00%									
Loss on extinguishment of debt							$ 400,000				
Effective interest rate of outstanding debt	11.63%						11.63%				
Line of credit, maturity date	Jan. 01, 2028	Jan. 01, 2028									
End of term fee percentage	5.50%										
End of term charge	$ 700,000										
Debt instrument, interest rate		9.25%									
Payment-in-kind interest rate		1.15%									
Loan amortization date		Jul. 01, 2025									
Percentage of total commitment amount		2.00%									
Total commitment amount		$ 50,000,000									
Term Loan | Wall Street Journal | Amended Loan Agreement											
Debt Instrument [Line Items]											
Term loan annual interest rate		0.75%									
Term Loan | Maximum | Wall Street Journal | Amended Loan Agreement											
Debt Instrument [Line Items]											
Debt instrument, interest rate		9.75%									
2021 Loan and Security Agreement | Hercules Capital											
Debt Instrument [Line Items]											
Term loan facility aggregate principal amount					$ 20,000,000						
Percentage of aggregate principle amount of term loan advances amount fee					6.35%						
Term loan maturity date					Jul. 01, 2025						
Term loan annual interest rate					8.25%						
Term loan reduced annual interest rate					8.15%						
Percentage of prepayment premium of principal amount outstanding of the closing date					3.00%						
Percentage of prepayment premium of principal amount outstanding prior to twenty-four months					2.00%						
Percentage of prepayment premium of principal amount outstanding prior to maturity date					1.00%						
Effective interest rate of outstanding debt								18.30%			
Note payable current	700,000						$ 700,000	$ 600,000			
Borrowed amount	22,500,000						22,500,000	11,000,000			
Debt discount and issuance costs	2,200,000						2,200,000	$ 1,100,000			
2021 Loan and Security Agreement | Hercules Capital | Prime Rate											
Debt Instrument [Line Items]											
Term loan annual interest rate					3.25%						
2021 Loan and Security Agreement | Tranche One | Hercules Capital											
Debt Instrument [Line Items]											
Term loan facility aggregate principal amount					$ 7,000,000						
2021 Loan and Security Agreement | Tranche Two | Hercules Capital											
Debt Instrument [Line Items]											
Term loan facility aggregate principal amount				$ 4,000,000							

Term loan facility, drawn term				2022-06			
2021 Loan and Security Agreement | Tranche Three | Hercules Capital							
Debt Instrument [Line Items]							
Term loan facility aggregate principal amount							$ 9,000,000
April 2023 Notes							
Debt Instrument [Line Items]							
Term loan maturity date			Jul. 31, 2023				
Loss on extinguishment of debt					$ 0		
Borrowed amount			$ 8,000,000				
Interest free period			45 days				
Fair value of debt instrument			$ 8,000,000				
Accrue interest rate percentage			15.00%				
April 2023 Notes | Minimum							
Debt Instrument [Line Items]							
Aggregate sale of convertible promissory notes, warrants, preferred shares, common shares, or combined thereof			$ 20,000,000				
Tranche 1 Advance | Term Loan | Amended Loan Agreement							
Debt Instrument [Line Items]							
Term loan facility aggregate principal amount	50,000,000					50,000,000	
Warrant issued to purchase preferred shares | shares		62,413					
Proceeds from line of credit	22,500,000						
Tranche 1 Advance | Term Loan | Amended Loan Agreement | Hercules Warrants							
Debt Instrument [Line Items]							
Borrowed amount	22,500,000					22,500,000	
Advance on loan allocated to warrants						300,000	
Tranche 3 Advance | Term Loan | Amended Loan Agreement							
Debt Instrument [Line Items]							
Term loan facility aggregate principal amount	$ 20,000,000					20,000,000	
Percentage of facility charge on amount borrowed	0.75%						
Applied to Refinance of Amount Outstanding | Term Loan | Prior Loan Agreement							
Debt Instrument [Line Items]							
Proceeds from line of credit	$ 8,600,000						
Tranche 2 Advance Subject to Achievement of Specified Interim Milestone | Term Loan | Amended Loan Agreement							
Debt Instrument [Line Items]							
Term loan facility aggregate principal amount	$ 7,500,000					$ 7,500,000	
Period Within Loan Disbursements to be Made	60 days						
Line of credit, maturity date	Mar. 31, 2025						
If Interim Milestone and Certain Clinical Milestones Achieved and No Default | Term Loan | Amended Loan Agreement							
Debt Instrument [Line Items]							
Loan amortization date		Jul. 01, 2026					
If Interim Milestone Achieved and No Default | Term Loan | Amended Loan Agreement							
Debt Instrument [Line Items]							
Loan amortization date		Jan. 01, 2026					

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Notes Payable - Schedule of Carrying Value of Term Loan (Details) - Term Loan - USD ($) $ in Thousands	**Oct. 31, 2024**	**Oct. 31, 2023**
Debt Instrument [Line Items]		
Note payable, including End of Term Charge	$ 24,663	$ 10,144
Debt discount, net of accretion	(1,673)	(474)
Accrued interest	182	108
Note payable, net of discount	$ 23,172	$ 9,778

~~XML 89 R63.htm IDEA: XBRL DOCUMENT~~

Notes Payable - Schedule of Estimated Future Principal Payments Due Under the Loan Agreement (Details) - 2021 Loan and Security Agreement $ in Thousands	**Oct. 31, 2024 USD ($)**
Debt Instrument [Line Items]	
2025	$ 699
2026	8,417
2027	10,987
2028	5,161
Note payable, net of discount	$ 25,264

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Convertible Debentures - Additional Information (Details) - USD ($)			**1 Months Ended**					**12 Months Ended**		
	May 16, 2023	**May 12, 2023**	**Oct. 31, 2023**	**Jun. 30, 2023**	**May 31, 2023**	**Apr. 30, 2023**	**Sep. 30, 2020**	**Oct. 31, 2024**	**Oct. 31, 2023**	**Oct. 31, 2022**
Short-Term Debt [Line Items]										
Convertible debentures			$ 0					$ 0	$ 0	
Initial maturity date							Sep. 28, 2023			
Change in fair value of convertible debentures embedded derivative liabilities									$ 21,421,000	
Fair Value, Net Derivative Asset (Liability), Recurring Basis, Unobservable Input Reconciliation, Gain (Loss), Statement of Income or Comprehensive Income [Extensible Enumeration]									Change in fair value of convertible debentures embedded derivative liabilities	Change in fair value of convertible debentures embedded derivative liabilities

Loss on extinguishment of convertible debentures								$ (366,000)		
Proceeds from Convertible Debt									$ 38,000,000	
Repayment of aggregate amount									3,176,000	
Cash			$ 81,500,000						$ 81,500,000	
Accrued interest percentage	10.00%									
Warrants to purchase shares of common stock			2,679,432						2,679,432	
Warrants, exercise price per share								$ 11.5		
Forbion Growth Sponsor FEAC I B.V										
Short-Term Debt [Line Items]										
Notes purchase principal amount				$ 20,000,000						
BDC Notes										
Short-Term Debt [Line Items]										
Convertible debt							$ 2,200,000			
Interest rate							8.00%			
Maturity date							Sep. 29, 2025			
Percentage of price per share							80.00%			
Percentage of principal							20.00%			
Embedded derivative liability measured at fair value							$ 200,000			$ 300,000
Change in fair value of convertible debenture embedded derivative liabilities									$ 300,000	
Interest expense, including the amortization of debt discounts									300,000	400,000
Debt issuance costs							$ 36,000			
Percentage of repay on closing date amount equal to principal		20.00%								
Loss on extinguishment								$ 9,000		
2022 Notes										
Short-Term Debt [Line Items]										
Convertible notes net										$ 18,400,000
Interest rate										10.00%
Initial maturity term										3 years
Embedded derivative liability measured at fair value										$ 3,500,000
Change in fair value of convertible debenture embedded derivative liabilities									21,200,000	
Interest expense, including the amortization of debt discounts									2,800,000	
Debt issuance costs										$ 44,000
Loss on extinguishment of convertible debentures									$ 3,100,000	
Conversion and exchange of redeemable convertible preferred stock into common shares in connection with the Reverse Recapitalization (in shares)									2,081,359	2,081,359
Modification of existing debt	$ 18,400,000									
Fair value of warrants	$ 500,000									$ 500,000
May 2023 Notes										
Short-Term Debt [Line Items]										
Initial maturity date	Oct. 20, 2025									
Debt issuance costs			$ 800,000						$ 800,000	
Fair value of warrants	$ 1,400,000									
Proceeds from Convertible Debt	30,000,000									
Accrued interest percentage					10.00%					
Fair value of debt instrument	$ 37,000,000		$ 56,200,000						$ 56,200,000	
Shares converted			4,298,463							
2023 Financing										
Short-Term Debt [Line Items]										
Borrowed amount				10,000,000	$ 28,000,000					
Cash				10,000,000	$ 20,000,000					
Warrants to purchase shares of common stock	2,679,432									
Warrants, exercise price per share	$ 11.5									
2023 Financing | Forbion Growth Sponsor FEAC I B.V										
Short-Term Debt [Line Items]										
Borrowed amount				$ 38,000,000						
April 2023 Notes										
Short-Term Debt [Line Items]										
Repayment of aggregate amount	$ 8,000,000									
Repayment						$ 8,000,000				

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Redeemable Convertible Preferred Shares - Additional Information (Details) $ / shares in Units, $ in Millions	**Jun. 30, 2021 USD ($) shares**	**Sep. 10, 2015 USD ($) shares**	**Jan. 06, 2015 USD ($) shares**	**Jul. 26, 2013 USD ($) shares**	**Oct. 31, 2024 $ / shares shares**	**Oct. 31, 2023 $ / shares shares**	**Oct. 31, 2023 $ / shares shares**	**Jun. 30, 2021 $ / shares shares**	**Jun. 30, 2021 $ / shares shares**	**Sep. 10, 2015 $ / shares**	**Sep. 10, 2015 $ / shares**	**Jan. 06, 2015 $ / shares**	**Jan. 06, 2015 $ / shares**	**Jul. 26, 2013 $ / shares**	**Jul. 26, 2013 $ / shares**
Class of Stock [Line Items]															
Warrants, exercise price per share | $ / shares					$ 11.5										
Warrants outstanding					8,511,968	10,411,641	10,411,641	10,242,130	10,242,130						
Share exchange ratio	0.18048														
Class C Second Tranche															
Class of Stock [Line Items]															
Initial aggregate amount that company agreed to sell	3,662,810														
Redeemable convertible preferred shares at a price per share | (per share)								$ 2.632	$ 2.13192						
Total aggregate proceeds | $	$ 7.8														
Share warrants issued								3,662,810	3,662,810						
Class A Redeemable Convertible Preferred Shares | Class A Initial Closing															
Class of Stock [Line Items]															
Initial aggregate amount that company agreed to sell				610,333											
Redeemable convertible preferred shares														$	$

at a price per share | (per share)													1.63845	1.5929
Total aggregate proceeds | $				$ 1.0										
Class A Redeemable Convertible Preferred Shares | Class A Second Tranche														
Class of Stock [Line Items]														
Initial aggregate amount that company agreed to sell				1,830,999										
Redeemable convertible preferred shares at a price per share | (per share)													$ 1.63845	$ 1.56967
Total aggregate proceeds | $				$ 2.9										
Class B Redeemable Convertible Preferred Shares | Class B Intial Closing														
Class of Stock [Line Items]														
Initial aggregate amount that company agreed to sell			2,758,221											
Redeemable convertible preferred shares at a price per share | (per share)											$ 2.17532	$ 1.85032		
Total aggregate proceeds | $			$ 5.1											
Class B Redeemable Convertible Preferred Shares | Class B Second Tranche														
Class of Stock [Line Items]														
Initial aggregate amount that company agreed to sell			1,838,815											
Redeemable convertible preferred shares at a price per share | (per share)											2.17532	1.63419		
Total aggregate proceeds | $			$ 3.0											
Class B Redeemable Convertible Preferred Shares | Class B Third Tranche														
Class of Stock [Line Items]														
Initial aggregate amount that company agreed to sell			1,608,963											
Redeemable convertible preferred shares at a price per share | (per share)											$ 2.17532	$ 1.63419		
Total aggregate proceeds | $			$ 2.6											
Class B-1 Redeemable Convertible Preferred Shares														
Class of Stock [Line Items]														
Initial aggregate amount that company agreed to sell		1,523,809												
Redeemable convertible preferred shares at a price per share | (per share)									$ 2.17532	$ 1.64367				
Total aggregate proceeds | $		$ 2.5												
Conversion ratio									1	1				
Series 1 Class C Redeemable Convertible Preferred														
Class of Stock [Line Items]														
Shares issued, price per share | (per share)					$ 1.63845	$ 1.5929								
Series 2 Class C Redeemable Convertible Preferred														
Class of Stock [Line Items]														
Shares issued, price per share | (per share)					2.175315	1.85032								
Series 3 Class C Redeemable Convertible Preferred														
Class of Stock [Line Items]														
Shares issued, price per share | (per share)					2.632	2.12376								
Share warrants issued							3,662,813	3,662,813						
Series 3 Class C Redeemable Convertible Preferred | Class C Inital Closing														
Class of Stock [Line Items]														
Initial aggregate amount that company agreed to sell	3,662,813													
Redeemable convertible preferred shares at a price per share | (per share)							$ 2.632	$ 2.12376						
Total aggregate proceeds | $	$ 7.8													
Series 4 Class C Redeemable Convertible Preferred														
Class of Stock [Line Items]														
Shares issued, price per share | (per share)					$ 2.10559	$ 1.69901								
Class C Warrants														
Class of Stock [Line Items]														
Share warrants issued							7,325,623	7,325,623						
Warrants, exercise price per share | (per share)							$ 2.632	$ 2.12376						
Warrants outstanding							10,242,130	10,242,130						
Warrant term	10 years													
Expiring term of warrants	Feb. 14, 2030													
Aggregate amount of shares exchanged							16,464,646	16,464,646						

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Common Shares - Additional Information (Details) - USD ($) $ / shares in Units, $ in Thousands			12 Months Ended				
	Oct. 24, 2024	Feb. 13, 2024	Oct. 31, 2024	Oct. 31, 2023	Dec. 22, 2023	Jan. 31, 2023	Jun. 30, 2021
Class of Stock [Line Items]							
Common stock shares authorized unlimited			Unlimited	Unlimited			
Common stock no par value							
Common stock shares outstanding			50,976,676	23,197,976			
Common stock voting rights			Common Shares are entitled to one vote				
Cash dividends declared			$ 0				
Share price			18				
Cash dividend paid			$ 0				
Warrants outstanding			8,511,968	10,411,641			10,242,130
Warrants, exercise price per share			$ 11.5				
Warrants exercisable period			30 days				

Warrants, maturity date			Oct. 31, 2028			
Warrants, maturity period			5 years			
Proceeds from exercises of warrants			$ 5,983			
Amended Loan Agreement						
Class of Stock [Line Items]						
Warrants, exercise price per share					$ 7.21	
Cashless Warrant Exercises						
Class of Stock [Line Items]						
Issuance of common shares			383,355			
Number of common stock warrants exercised by investors on cashless basis			1,379,391			
Cash Warrant Exercises						
Class of Stock [Line Items]						
Issuance of common shares			520,282			
Proceeds from exercises of warrants			$ 6,000			
February 2024 Subscription Agreements						
Class of Stock [Line Items]						
Aggregate gross proceeds of common stock		$ 200,000				
Date of closed private placement			Feb. 20, 2024			
Offering expenses		$ 12,400				
February 2024 Subscription Agreements | Private Placement						
Class of Stock [Line Items]						
Common shares price per share		$ 10				
Issuance of common shares		20,000,000				
October 2024 Subscription Agreements						
Class of Stock [Line Items]						
Aggregate gross proceeds of common stock	$ 60,100					
Date of closed private placement			Oct. 29, 2024			
Offering expenses	$ 3,800					
October 2024 Subscription Agreements | Private Placement						
Class of Stock [Line Items]						
Common shares price per share	$ 8.9					
Issuance of common shares	6,758,311					
FEAC						
Class of Stock [Line Items]						
Common stock shares outstanding				3,670,927		
Warrants outstanding			8,449,555	5,029,444		
Warrants, exercise price per share			$ 11.5			$ 7.21
Warrants, maturity date			Dec. 22, 2030			
Warrants, maturity period			7 years			
FEAC | Amended Loan Agreement						
Class of Stock [Line Items]						
Warrants outstanding			62,413			

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Common Shares - Schedule of Shares Reserved For Future Issuance Under The Plan (Details) - shares	**Oct. 31, 2024**	**Oct. 31, 2023**
Class of Stock [Line Items]		
Common stock shares reserved for future issuance	17,299,369	15,726,525
Remaining shares reserved for future issuance under the equity plans		
Class of Stock [Line Items]		
Common stock shares reserved for future issuance	2,752,889	2,607,943
Options to purchase common shares		
Class of Stock [Line Items]		
Common stock shares reserved for future issuance	6,034,512	2,706,941
Warrants to purchase common shares		
Class of Stock [Line Items]		
Common stock shares reserved for future issuance	8,511,968	10,411,641

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Common Shares - Schedule of Shares Reserved For Future Issuance Under The Plan (Parenthetical) (Details)	**Jul. 07, 2023 shares**
Equity [Abstract]	
Shares Vesting	252,121

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					12 Months Ended					
Share-Based Compensation - Additional Information (Details)	**May 15, 2024 shares**	**Feb. 13, 2024 USD ($) shares**	**Jul. 07, 2023 $ / shares shares**	**Jul. 05, 2018**	**Oct. 31, 2024 USD ($) $ / shares shares**	**Oct. 31, 2024 USD ($) $ / shares $ / shares shares**	**Oct. 31, 2023 USD ($) $ / shares shares**	**Oct. 31, 2023 USD ($) $ / shares $ / shares shares**	**Jan. 02, 2024 shares**	**Jul. 07, 2023 $ / shares shares**
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Exchange ratio					0.18048%		0.18048%			
Stock-based compensation expense | $					$ 5,324,000		$ 3,450,000			
Unrecognized compensation expense | $					$ 22,100,000	$ 22,100,000				
Common stock shares reserved for future issuance					17,299,369	17,299,369	15,726,525	15,726,525		
Shares Granted					3,591,200					
Exercise price | $ / shares					$ 6.88	$ 6.88	$ 2.4	$ 2.4		
Issued options fully vested			794,643							
Remaining options vesting			252,121							252,121
Award vesting period			4 years							
Unrecognized compensation expense weighted-average period of recognition					3 years 5 months 19 days					
Stock options exercised					116,752					
Weighted-average grant-date fair value per share of share options granted | $ / shares						$ 7.3		$ 2.96		
Employee Stock Option [Member]										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Stock-based compensation expense | $							$ 2,600,000			

Common stock shares reserved for future issuance					6,034,512	6,034,512	2,706,941	2,706,941		
Shares Granted			1,046,764							
Exercise price | (per share)			$ 5.87							$ 4.24
CEO Transition Agreement										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Incremental compensation cost | $		$ 1,000,000								
CEO Transition Agreement | Former CEO										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Shares Granted		1,216,266								
Award vesting period		12 months								
Payment Of Target Annual Bonus Netoff Taxes And Withholdings | $		$ 390,000								
Amount of monthly fee for consulting period | $		$ 25,000								
Initial consulting Period		6 months								
Transition services for consulting fee per hour | $		$ 500								
Maximum hours of ceo devote per week to providing transition services		15 hours								
Severance Agreement										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Shares Granted					231,684					
Incremental compensation cost | $					$ 300,000					
Employee entitled for continued pay and health insurance benefits					12 months					
The Old Plans										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Stock-based compensation expense | $					$ 400,000					
Unrecognized compensation expense | $					$ 0	$ 0	$ 0	$ 0		
Common stock shares reserved for future issuance							2,706,941	2,706,941		
Options to purchase common shares							2,706,941	2,706,941		
Incremental compensation cost | $							$ 0			
Number of options remain available for grant							0	0		
The Old Plans | Maximum										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Percentage of issuance of common stock options				15.00%						
The Old Plans | Maximum | Employee Stock Option [Member]										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Stock options vesting service period				4 years						
The Old Plans | Minimum | Employee Stock Option [Member]										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Stock options vesting service period				3 years						
2023 Plan										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Common stock shares reserved for future issuance					7,261,110	7,261,110	2,607,943	2,607,943		
Common stock capital shares reserved for remaining future issuance					2,752,889					
Increase in number of share reserved for future issuance in the beginning of the year							1,946,226			
Number of shares authorized increased									1,946,226	
2023 Plan | Employee Stock Option [Member]										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Percentage of common stock value on date of grant					100.00%					
2023 Plan | Maximum | Employee Stock Option [Member]										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Stock option term							10 years			
2023 Plan | Evergreen Provision										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Increase in number of share reserved for future issuance in the beginning of the year	1,946,226									
Aggregate number of common shares outstanding percentage	5.00%									
Issuance of common shares	2,500,000									
Inducement Grants										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Shares Granted					1,643,000					
Exercise price | $ / shares					$ 8.69	$ 8.69				
Award vesting period					4 years					
Stock option term					10 years					
Non-Voting Common Shares										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Additional awards approved for issuance			1,046,764							1,046,764
Common stock shares reserved for future issuance			1,775,729		2,822,493	2,822,493				1,775,729
Vesting Immediately Upon Grant Date | The Old Plans | Employee Stock Option [Member]										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Percentage of vesting rights				100.00%						
Vesting Immediately Upon Grant Date | Inducement Grants										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Percentage of vesting rights					25.00%					
Vesting on Remaining Years | Inducement Grants										
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]										
Award vesting period					3 years					

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Share-Based Compensation - Schedule of Assumptions Used to Determine Grant-Date Fair Value of Stock Options (Details) - Employee	12 Months Ended		
	Oct. 31, 2024 $ / shares	Oct. 31, 2023 $ / shares	Oct. 31, 2023 $ / shares

Stock Option [Member]			
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]			
Expected volatility, Minimum	78.24%	79.92%	79.92%
Expected volatility, Maximum	82.33%	81.48%	81.48%
Risk-free interest rate, Minimum	1.78%	3.56%	3.56%
Risk-free interest rate, Maximum	4.66%	4.35%	4.35%
Fair value of common shares and exercise price of options, Minimum | (per share)	$ 4.73	$ 2.11	$ 1.52
Fair value of common shares and exercise price of options, Maximum | (per share)	$ 12.6	$ 12.36	$ 8.93
Minimum			
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]			
Expected term (in years)	5 years 6 months 3 days	5 years 2 months 12 days	5 years 2 months 12 days
Maximum			
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]			
Expected term (in years)	6 years 29 days	6 years 29 days	6 years 29 days

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Share-Based Compensation - Summary of Stock Option Activity (Details) - USD ($) $ / shares in Units, $ in Thousands	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Share-Based Payment Arrangement [Abstract]		
Number of shares outstanding, Beginning balance	2,706,941	
Granted	3,591,200	
Exercised	(116,752)	
Forfeited or expired	(146,877)	
Number of shares outstanding, Ending balance	6,034,512	2,706,941
Options vested and exercisable	2,497,082	
Options unvested	3,537,430	
Weighted-Average Exercise Price Outstanding, Beginning balance	$ 2.4	
Weighted-Average Exercise Price, Granted	10.18	
Weighted-Average Exercise Price, Exercised	0.97	
Weighted-Average Exercise Price, Forfeited or expired	6.71	
Weighted-Average Exercise Price Outstanding, Ending balance	6.88	$ 2.4
Weighted-Average Exercise Price, Options vested and exercisable	2.32	
Weighted-Average Exercise Price, Options unvested	$ 10.1	
Weighted- Average Remaining Contractual Term (in years), Outstanding	7 years 4 months 24 days	8 years 1 month 6 days
Weighted- Average Remaining Contractual Term (in years), Options vested and exercisable	4 years 4 months 24 days	
Weighted- Average Remaining Contractual Term (in years), Options unvested	9 years 7 months 6 days	
Aggregate Intrinsic Value, Outstanding	$ 17,809	$ 52,192
Aggregate Intrinsic Value, Options vested and exercisable	16,311	
Aggregate Intrinsic Value, Options unvested	$ 1,498	

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Share-Based Compensation - Summary of Share-based Compensation Expense (Details) - USD ($) $ in Thousands	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]		
Total share-based compensation expense	$ 5,324	$ 3,450
Research and Development		
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]		
Total share-based compensation expense	1,794	780
General and Administrative		
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]		
Total share-based compensation expense	$ 3,530	$ 2,670

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Net Loss Per Share - Summary of Basic and Diluted Net Loss Per Share (Details) - USD ($) $ / shares in Units, $ in Thousands	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Numerator:		
Net loss	$ 55,142	$ 99,917
Deemed dividend attributable to redeemable convertible preferred shareholders		4,822
Net loss attributable to common shareholders, basic	55,142	104,739
Net loss attributable to common shareholders, diluted	$ 55,142	$ 104,739
Denominator:		
Weighted-average number of common shares used in net loss per share, basic	37,782,346	692,609
Weighted-average number of common shares used in net loss per share, diluted	37,782,346	692,609
Net loss per share of common shares, basic	$ 1.46	$ 151.22
Net loss per share of common shares, diluted	$ 1.46	$ 151.22

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Net Loss Per Share - Summary of Diluted Net Loss Per Share Attributable To Common Shareholders (Details) - shares	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Antidilutive Securities Excluded from Computation of Earnings Per Share [Line Items]		
Shares excluded from computation of diluted net loss per share	14,546,480	13,118,582
Warrants to purchase common shares		
Antidilutive Securities Excluded from Computation of Earnings Per Share [Line Items]		
Shares excluded from computation of diluted net loss per share	8,511,968	10,411,641
Options to purchase common shares		
Antidilutive Securities Excluded from Computation of Earnings Per Share [Line Items]		
Shares excluded from computation of diluted net loss per share	6,034,512	2,706,941

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Income Taxes - Summary of Loss Before Provision for Income Taxes (Details) - USD ($) $ in Thousands	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Income Tax Disclosure [Abstract]		

Domestic (Canada)	$ (53,460)	$ (99,157)
Foreign (US)	(1,701)	(743)
Loss before income taxes	$ (55,161)	$ (99,900)

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Income Taxes - Summary Of Components Of The Provision For (Recovery Of) Income Taxes (Details) - USD ($) $ in Thousands	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Current expense (benefit):		
Foreign (US)	$ (19)	$ 17
Total current expense (benefit)	(19)	17
Deferred expense (benefit)		
Total income tax expense (benefit)	$ (19)	$ 17

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Income Taxes - Summary of Reconciliation of Company's Statutory Income Tax Rate (Details)	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Income Tax Disclosure [Abstract]		
Income at Canadian statutory rate	26.50%	26.50%
Conversion of debentures		(21.90%)
State taxes, net of federal benefit	0.18%	0.05%
Permanent differences	(2.77%)	1.68%
Tax credits	1.07%	0.19%
Foreign rate differential	(0.17%)	(0.04%)
Valuation allowance	(25.02%)	(6.52%)
Other	0.24%	0.03%
Effective income tax rate	0.03%	(0.01%)

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Income Taxes - Summary of Net Deferred Income Tax (Details) - USD ($) $ in Thousands	Oct. 31, 2024	Oct. 31, 2023
Deferred tax assets:		
R&D expenditures	$ 8,172	$ 7,012
Net operating loss (NOL) carryforwards	31,661	18,918
Capital loss carryforwards	97	
Investment tax credits, net	1,934	1,210
Property and equipment	704	791
Financing costs	5,452	2,440
Accruals	747	149
Section 174 capitalized R&D costs		393
Operating lease liability	404	
Note payable	197	
Other	1	172
Total deferred tax assets	49,369	31,085
Deferred tax liabilities:		
Operating lease-right of use asset	(377)	
Total deferred tax liabilities	(377)	
Valuation allowance	$ (48,992)	$ (31,085)

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Income Taxes - Additional Information (Details) - USD ($)	12 Months Ended	
	Oct. 31, 2024	Oct. 31, 2023
Income Tax Contingency [Line Items]		
No uncertain tax positions	$ 0	$ 0
Accrued interest related to unrecognized tax benefits	0	0
Accrued penalties related to unrecognized tax benefits	0	0
Capital losses	700,000	
SR&ED expenditures		32,500,000
Federal		
Income Tax Contingency [Line Items]		
Net operating loss carryforwards	1,900,000	
U.S		
Income Tax Contingency [Line Items]		
Net operating loss carryforwards	$ 1,400,000	
U.S | Earliest Tax Year		
Income Tax Contingency [Line Items]		
Investment tax credits expiration year	2041	
U.S | Latest Tax Year		
Income Tax Contingency [Line Items]		
Investment tax credits expiration year	2043	
Canadian		
Income Tax Contingency [Line Items]		
Net operating loss carryforwards	$ 113,100,000	
Investment tax credits	$ 2,600,000	
Canadian | Earliest Tax Year		
Income Tax Contingency [Line Items]		
Net operating loss carryforwards expiration year	2029	
Investment tax credits expiration year	2025	
Canadian | Latest Tax Year		
Income Tax Contingency [Line Items]		
Net operating loss carryforwards expiration year	2044	
Investment tax credits expiration year	2044	
Canadian | Federal		
Income Tax Contingency [Line Items]		
Net operating loss carryforwards	$ 119,100,000	
SR&ED expenditures		$ 29,600,000
Canadian | Federal | Earliest Tax Year		
Income Tax Contingency [Line Items]		
Net operating loss carryforwards expiration year	2026	
Canadian | Federal | Latest Tax Year		
Income Tax Contingency [Line Items]		

Net operating loss carryforwards expiration year	2044

~~*XML 106 R80.htm IDEA: XBRL DOCUMENT*~~

				1 Months Ended		12 Months Ended	
Leases - Additional Information (Details)	**Jan. 01, 2024 USD ($) ft²**	**Dec. 29, 2022 ft² $ / ft²**	**Apr. 30, 2023**	**Oct. 31, 2022 USD ($)**	**Nov. 30, 2021 USD ($) ft²**	**Oct. 31, 2023 USD ($)**	**Oct. 31, 2024 USD ($)**
Lessee, Lease, Description [Line Items]							
Operating lease right of use assets							$ 1,741,000
Operating lease liabilities						$ 0	1,850,000
Additional lease commitments to be paid							$ 3,238,000
Office Space							
Lessee, Lease, Description [Line Items]							
Rentable square feet | ft²	6,450						
Aggregate amount of base rental payments	$ 500,000						
Lease expiration date	Dec. 30, 2026						
Operating lease right of use assets	$ 400,000						
Operating lease, option to extend	false						
Office and Lab Space							
Lessee, Lease, Description [Line Items]							
Rentable square feet | ft²					9,360		
Operating lease commencement period					2021-11		
Lease expiration date					Oct. 31, 2022		
Operating lease initial term					12 months		
Operating lease renewal term				6 months	12 months		
Operating lease right of use assets					$ 0		
Operating lease liabilities					$ 0		
Lease expiration month and year			2023-09	2023-04			
Operating lease, option to extend				true		true	
Operating lease extended term				2023-09			
Additional lease commitments to be paid				$ 200,000			
New Laboratory and Office Space							
Lessee, Lease, Description [Line Items]							
Rentable square feet | ft²		10,620					
Operating lease commencement period		2023-11					
Operating lease initial term		10 years					
Initial annual base rent | $ / ft²		36.50					
Percentage of increase in annual base rent		2.00%					

~~*XML 107 R81.htm IDEA: XBRL DOCUMENT*~~

	12 Months Ended	
Leases - Schedule of Components of Operating Lease Cost (Details) - USD ($) $ in Thousands	**Oct. 31, 2024**	**Oct. 31, 2023**
Lease Cost:		
Operating lease cost	$ 444	
Variable operating lease cost	24	$ 62
Short-term operating lease cost		411
Total operating lease cost	$ 468	$ 473

~~*XML 108 R82.htm IDEA: XBRL DOCUMENT*~~

	12 Months Ended
Leases - Summary of Cash Paid for Amounts Included in the Measurement of the Operating Lease Liabilities (Details) $ in Thousands	**Oct. 31, 2024 USD ($)**
Leases [Abstract]	
Cash paid for amounts included in the measurement of operating lease liabilities	$ 365

~~*XML 109 R83.htm IDEA: XBRL DOCUMENT*~~

Leases - Schedule of Maturities of Operating Lease Liabilities (Details) - USD ($) $ in Thousands	**Oct. 31, 2024**	**Oct. 31, 2023**
Leases [Abstract]		
2025	$ 452	
2026	464	
2027	323	
2028	299	
2029	305	
Thereafter	1,395	
Total	3,238	
Less: Interest	(1,388)	
Total lease liability	$ 1,850	$ 0

~~*XML 110 R84.htm IDEA: XBRL DOCUMENT*~~

					12 Months Ended	
Related Party Transactions - Additional Information (Details) - USD ($)	**Oct. 29, 2024**	**Feb. 20, 2024**	**May 16, 2023**	**Apr. 04, 2023**	**Oct. 31, 2024**	**Oct. 31, 2023**
Related Party Transaction [Line Items]						
Amount of convertible debentures and warrants			$ 38,000,000			
Cash						$ 81,500,000
Initial maturity period			3 years			
Accrued interest percentage			10.00%			
Dividends or distributions declared or paid						$ 0
Exchange ratio					0.18048%	0.18048%
Common stock shares issued					50,976,676	23,197,976
Warrants to purchase shares of common stock						2,679,432
2024 PIPE Investors						
Related Party Transaction [Line Items]						
Issuance of common shares	561,797	800,000				
Issuance of common shares, value	$ 5,000,000	$ 8,000,000				
Private Placement | 2024 Subscription Agreements						
Related Party Transaction [Line Items]						
Issuance of common shares	6,758,311	20,000,000				
Common shares price per share	$ 8.9	$ 10				
Company Shareholders						
Related Party Transaction [Line Items]						
Amount of convertible debentures and warrants			$ 8,000,000			

Forbion Growth Sponsor FEAC I B.V				
Related Party Transaction [Line Items]				
Amount of convertible debentures and warrants	20,000,000			
Common stock shares issued				2,262,351
Number of securities into which the class of warrant or right may be converted				950,153
Investissement Quebec				
Related Party Transaction [Line Items]				
Amount of convertible debentures and warrants	10,000,000			
FEAC				
Related Party Transaction [Line Items]				
Common stock shares issued				3,670,927
Number of securities into which the class of warrant or right may be converted				5,029,444
Old enGene's Equity and Convertible Note Holders				
Related Party Transaction [Line Items]				
Common stock shares issued				13,091,608
April 2023 Notes				
Related Party Transaction [Line Items]				
Principal amount		$ 8,000,000		
Interest rate		15.00%		
Amount of convertible debentures and warrants		$ 8,000,000		
Maturity date		Jul. 31, 2023		
Settlement and extinguishment		$ 8,000,000		
Repayment	8,000,000			
May 2023 Notes				
Related Party Transaction [Line Items]				
Amount of convertible debentures and warrants	30,000,000			
May 2023 Financing				
Related Party Transaction [Line Items]				
Amount of convertible debentures and warrants	28,000,000			
Cash	20,000,000			
June 2023 Financing				
Related Party Transaction [Line Items]				
Principal amount	10,000,000			
Cash	$ 10,000,000			
Minimum				
Related Party Transaction [Line Items]				
Percentage of shares owned by shareholders			10.00%	10.00%
Minimum | April 2023 Notes				
Related Party Transaction [Line Items]				
Aggregate sale of convertible promissory notes, warrants, preferred shares, common shares, or combined thereof		$ 20,000,000		

~~***XML 111 R85.htm IDEA: XBRL DOCUMENT***~~

Subsequent Events - Additional Information (Details) - Subsequent Event - Term Loan	Dec. 18, 2024 USD ($)
Amended Loan Agreement	
Subsequent Event [Line Items]	
Line of credit, maximum amount available	$ 50,000,000
First Amendment	
Subsequent Event [Line Items]	
Percentage of facility charge on amount borrowed	0.75%
Advance Subject to Achievement of Specified Interim Milestone | First Amendment	
Subsequent Event [Line Items]	
Line of credit, maximum amount available	$ 7,500,000
Loan Advance | First Amendment	
Subsequent Event [Line Items]	
Line of credit, maximum amount available	$ 27,500,000

~~EXCEL 112 Financial_Report.xlsx IDEA: XBRL DOCUMENT begin 644 Financial_Report.xlsx M4$L#!!0 (-B"DUD'04UB@0 +$ 0 9&]C4')O<',O87!P+GAM
M;$V./0L",1!$_\IQO;=!P4)B0-!2L+(/>QLOD&1#LD)^OCG!CVX>;QA&WPIG M*N*I#BV&5(_C(I(/ !47BK9.7:=N')=HI6-Y #OGDK7A.YNJQ<&4GPZ4A!0W_J=0U[R;UEA_6\#MI7E!+
P04 M " #8@I-9IH M8>X K @ $0 &1O8U!R;W!S+V-O&ULS9)1 M2\,P$,>_BN2]O295P=#E9<,G!<&!XEM(;EM8TX3DI-VWMZU;A^@'\#%W__SN M=W"-B=*$A"\I1$SD,-\,ONVR-
''%#D11 F1S0*]S.2:ZL;D+R6L:GVD/49NC MWB.(JKH'CZ2M)@T3L(@+D:G&&FD2:@KIC+=FP%W%?;!NIW[MQ\870=7 K[M07U!+ P04 " #8@I-9F5R<(Q & "<)P $P 'AL+W1H
M96UE+W1H96UE,2YX;6SM6EMSVC@4?N^OT'AG]FT+QC:!MK03621A'^_1S80RY8-[9)-NIL\!"SI^\Y%1^?H.'GS[BYBZ(:(E/)X M8-DOV]:[MR_>X%#BVR]*+ M41B1%G\@M
MNN01.+5)#3(3/PB=AIAJ4!P"I DQEJ&&^+3&K!'@$WVWO@C(WXV(JZMOFCU7 MH5A)VH3X$$8:XIQSYG/1;/L'I4;1]E6\W*.76!4!EQC?-*HU+,76>)7 \:V< M/!T3$LV4"P9!AI@S
M&L%&KQMUAVC2/'K^!?F<-0HACA*FNVB<5@$_9Y>PTG!Z(++9OVX?H;5,VPLCO='U!=*Y \FIS_I,C0' MHYI9";V$5FJ?JH,@H%\;D>/N5Z> HWEL:\4*Z">P'_T=HWPJOX@L Y M?
RY]SZ7ON?0]H=*W-R-]9\'3BUO>1FY;Q/NN,=K7-"XH8U=RSTS0LS0[=R2^JVE+ZU)CA* M]+',<$X>RPP[9SR2';9WH!TU^_9==N0CI3!3ET.X&D*^ VVZG=PZ.)Z8D;D*
MTU*0;\/YZ<5X&N(YV02Y?9A7;>?8T='[Y\%1L*/O/)8=QXCRHB'NH8:8S\-# MAWE[7YAGE<90-!1M;*PD+$:W8+C7\2P4X&1@+: '@Z]1 O)256 Q6\8#*Y"B M?$R,1>APYY=
<7^/1DN/;IF6U;J\I=QEM(E(YPFF8$V>KRMYEL<%5'<]56_*P MOFH]M!5.S_Y9KF4Q9Z;RWRT,"2Q;B%D2XDU=[=7GFYRN>B)V^I=W MP6#R_7#)1P_E.^=?]%U#KG[VW>/Z;I,
[2$R<><41 71% B.5' 86%S+D4.Z2 MD 83 >LX=SFWJXPD6L_UC6'ODRWSEPVSK> U[F M$RQ#I'[!?8]*@!&K8KZZKT_Y)9P[M'OQ@2";_-;;I/;=X Q\U*M:I60K$3]+ M!WP?
D@9CC%OT-%^/%&*MIK&MQMHQ#'F 6/,,H68XWX=%FAHSU8NL.8T*;T'5 M0.4_V]0-:/8--!R1!5XQF;8VH^1."CS<_N\-L,+$CN'MB[\!4$L#!!0 (M -B"DUDGO]2&PO=V]R:W-
H965T&UL MM5QMG?M! 3EF"L@KR7GY M]_M(8&-ZA8"]2HCU[_T^#U,X$@%I4G?'0Q&_13'6>_B3'TW9Q=G=".2."-S MAO@F33%[_4 2^GS>,_C4WZ%$<4HR'M,, M,;(\
[TV>]@2P124@H) 2&/T\D($DB MD: @O=TU9>#^\1;]2E4>*O. .0EH\BV.Q.J\-^ZAB"SQ)A%W]/D3*2HT ME'@A3;CZ'ST7YPYZ*-QP0=,B&$J0QEG^%[\41+0)<(L]Z< QZ\)\(H KVV
M7P3XBIF*HJ'*1;XXHS19\3DV8 F#Q29*AJJ'V>RW1>"P:\QQ(F+*0TWT(P" MX2Q"EYF(Q2N:97D^R78Y1E\74_3FU[=G?0&7DT']L(#^D$.[-=".B[[03*PX
MX$8DJ@+TH9R[PKK;PGYPC8BWH3A!GG.$W('K:PH4F,.G)#Q!SJ@V?&H.GZP9 M7'V@"Z_4QMM1[RD\KP:O8/LZYB+.'CGZZQI.0#-!4OY?'=LYFJ]'D_W#[WR- M0W+>@PZ
$_9$>A>__>*,!N]U3-D$FUH"J[#H[UCT3>AE M^_KHF.-G.X,SC^ MK./'&-65'TM@%7Z&.WZ&Q@I.@)Q($725X$<=0>;X)4ZXCM? &-:5(4M@%89& M.X9&[3)HDF4;G*
[LJ9,Z)@RXPBVT1)EC.I*E"6P"E&G.Z).6]YJ#,/ K\:' M>K+,6+5I90SKRI8EL I;XQU;XW9LS0F+J1Q<(P1#M+:/,B/MAKW:<<\8WY4T M2V 5TM[M2'O7CK2KF(=P+WXGF*$K^)+K:#-
CU9%EC.I*EB6P"EG.H!1O V,5 M"PEQ%2<$W6S2!*T,LT,,A@XQ[XS'FK),L=V9BB M G-49]8.H?"=4N([9HV^\^V"L'PB12H-O*51RYH9L8XUJZ+?%EJ5M5+V.V:]
M/@NN[M!D$\6",C01@G"1SWG4&:4&O%I):X[KS-HA+(!3>@#'+-SW) =# >C9 M1\I>M6R9<6YH=HS#D ,@$0YH)8]JX[%EJ5O=(3.&8IO^W8]N6MR1@TP!T? M.X-
CS]'29M43V$*KTE:Z J>;+2@L5:TQ:("[^JYES*HQL(56G2@MG8';RAF M,*4,QE#5L1VI490@Z.X""F(MA (VW>-:!/M"EG#NI*H"VT*H&E5W!;>84 MLHY!QLVRB+R@ST3;U35
#GO: #D8'_R?UKVK%H%6VA5]DJKX)H%_EXWE^$LC"'OU!VKOKMD M3-VX,(#D2V9_29VB72EHN$RM4#''=2;S$%;"+:V$V\I*+%*<).C#AL//7#M8
M-.#43>N:PSJ3=0@'X98.PFWE("Y3PAZEW?H("&(%V9:N<:;O\|R M:Q9=1"V MT*JLE0["-2O^;8JM"*28B:M_:1S,<9W).H1Q<$OCX+8R#I,H G1^M#U :M7S M-M/+$#.D/QZ-
T=V&H&OR] KJ9A.#NG%=_4!AU4;80JMR6=H(UZS[?^8RD)]@ M=+BGSYF61S/< L>9.+[&FYK9@L 3A3/&7V*LU"? MB6;,/P(M;58=A2VTZF:%TE%XK1Q%F7.YA=#N5#
C!1/MC@2K[L$66I6LTCUX MK=S#CJPYY0+4W'_B=:WE:D#\Y-\A=Z[U7>;(SLP=PD%XI8/PS')?=6431G] M46: H:-=R#)'=2;I$$;!V]LY9%;PUU3-@JQH9EKW:P#Q//?8'X_'6K;L[@\Z
MA!/P2B?@M7("ER_[&Q?R*20M;?_.#YC#.E-V"#_@E7[:^4'YIN') [154*Q M=A7!C-)Y3YI5;U"@#16:W/[Z=#'TO-%@.#X=G?6?=/24PM]K)?Q!\J>02@M! MPQ^@(U88BH5N-
P+Z^DPN#&LILZGI@P)MM%_)P;O3T6BOC@4=AU#_7JG^O79[MA_C>E"2)T(-AM_7)Y<[] LYO@]FY^>S>YOYRB#]_1 MW>75Y=WE37)XS&3O0!'=(G$BLB=PG$6JY6S-
:,OKXCOYEW@#-UR/Q(4/1"T MC!.HQA+48PQUD;\WLN]{(V^9,!9OC_(K8;Y"RX0^9592]:R M_C)]P;#)Y%TSZ'_B=4*X=M.2^6;JW'DVT*J;Z$MW[S>LZ!4\26ES??
M/B'D6WU$R"K:U!9:E M)\U*'*H_=5Q3H8#!/(Y/U-+N4TS'%A%F]I"J[9#::W]L=T!QJ8U"*RB36VA M5:DLC89O=@HM!IB&94D88+YI:;+J,VRA51]&+7W&T&P2.HPP#4CM^Y#%_]V'
M!..R='[.]1"^95CZEJ'9=;0?K1J ZDVQ+D?B?UU@F.U/1(M_N*$W;>[-UM,U/L<^N7I^6LQOF"Y78JCA"PA='!R"C*$Y6^:R#\(NE;O7GB@ M0M!4':X(C@B3)\#O2TK%]H.\P.Y]'Q?_%!+
P04 " #8@I-9$C<0[]\% M !]& & 'AL+W=O+G]I ^[C6@IX*!'@>P4R$L5_)V"7SNZ15:[=4$UG9Y*<8^DD09KYJ'> MFUH;O.&E.<:YEO K!ST]G5U]F5]]_G1Q?G-Y@=Z??
S[_,KM$\X^7ES=S=(2^ MS2_0'V_^1&\0+]'-2E2*E@MU.M&PLM&?9+M5WF]7(3VK7&7Z&/EXC(A' H?Z M[.7J_J'Z!/S=.TWV3I/:GM_G="4E*S6B2C&M3ES^; T$;@,FMT[4FF;L; 3)
MHYC?>+C!WXZN]]]8>L3V=4K1"<&LK,_M1\0W-P7GG*6Y- MA;4I4P V4QS[G@='MFG[8XLE."1X+W4 --@##0:!_D7E=Z;I;9, M00RJE9 ::28+%^*MS:@%)0I]DG0 #Z[\R@,
(]WZ%@WY]94I+GFFV@"3:P$O1 MM_NAY4M,.HXX1"+WMD=[>-$@O$][3$C3!Y1)MN!:087.&$0*G(8+:63!\/TN M5%N&^('O!AOOP<:#8*\E6U.^J.-9Z!634"+;J>S"&ELXDHA$';"V$
X]SPTV MV8--!L'>"$WS%P!,[(T*8C_J[JG,NM9"$:4CB M#M[!A5^9<]AK:,U[)E*@TY'ZL0X54_76)L3'J&3:25^>'0 X2CLN.:3")'6? M &XQ,!Z$>@5 J>:PX3F#A@1)TWD@L405O/2'S<[J
>0XP%W(@VN_]A@:HL6# MW#:]JI-TP EB.^'"7;YQ2*5^3^3CAACQ,#-N\W, FV]7.8R!$+OH;+DD2L.^ MN&CX$ FLU7!OXC==M[\'UR)&[+$PVQYGF6B GY$:_K8QS[8
M9D$<8"OR'5(X[&%+W- E'N9+ "@KX'+V).4@F)I]@?/!)R"2) M8 JOV#M4@7C!S7"X_1W12L/ R_]EBS$*O7$:1^,HCFJ6(?X8I['YZDF8*V6X MJ*:@2BL-#R;.Q\P#LN3KTTL0B
M68<<"5._-U2:/H \TPM@"@@EE;FNG,#A4A3ZW;-.78XY%QCQZ1U-VPN MYF'BO^.E DI<@IYW'(,!N;WKWKYHL:ZOBV^%UJ*H'U>, FHC +\O!30#NQ=S M [W_C\/T/U!+ P04 "
#8@I-9=$U:/Y$" Z!P & 'AL+W=OQ@K#$3%L&8EY+3+$L+9&1\7/-Z;4E M+7![O&'_YKP;+X]$82K*'S37Q=#[ZD&.)#52@NV!AL%C/+F39[7^[%Z$8' ,$:$+P$] X
PC4@=$8;9<[6.=$DB:58 M@;39ALT.W-XXM'%#N?V*,RW-*C4XG:2W-[/;J\OST?WD',:CJ]%-.H'9Q61R M/X./4R*1ZP(US4CY";[!_!!%2:J8E^;ZI;#S]:5QDVEX$"E;@#7PK IF/ <
M\UT"W\ANM0<;[>/@*.-MID\@['Z&H!/T]@A*WPX/C\@)VZT,'5_OT%8*QLR/ M:3Y9]@1<0$4D+$E9X[Z].DIEC^Z9JDB&0\^<385RB5X"^RS^/\^.UU[KM?=V MK\T? :36A9#T-
^90&P"C^N57;JP?9WXX DW_";ICL-\:[+_;(%6]WF^IX8H< ME^V;RZ3?.1U$T2"*_>6V@=>)0=@]'9QN)>[(C5]YT;OEFIZM-.$YY8M]FJ.W M:GZ=>$"SO]6&&,J%Z\X*,E%SW9SJ-MI>
"/7]U[$Q^9B:/KX7YKF5KDFQ3:M$XW+,SEAM(FF/6Y$'HSL07:ZS+Y U!+ M P04 " #8@I-980[>. <& '&@ & 'AL+W=O#(I%
MPC):'(DUR^'-4LB,*KB5JT&QEHS&9:,L'1#/"P<9Y7EO'>TX-[ODJ4?C"8G*SIBLV8^K:^DW W:+S$/&-YP46. M)%N>]L[P\=3W=(/2XCMGNV+O&FDJ2!S)P6;"K2'SQ6R6EOW$,Q6])-
JN[%[@NK"0VU MOX5(B_(7[6I;KX<6FT*)K&X,"#*>5__TL1Z(O08X[&A Z@;DL$'0T<"O&_@E MT0I92>N"*CHYD6*'I+8&;_JB')NR-;#AN9[&F9+PED,[-9G>WLQNOUY=G#U<
M7J#9_Q=7]X\S-#M)W1[=WE_]G %!NCLY@)-;Z_O[B^_7-[,KKY?HJ^WLQGJ MHV^S"_3^W0?T#O$FTLYWX8Q\/3P;;?3:F%0Z# MX;BQ>@9SV, <.F%^9CG,2UJBI#'$%R^4GJA~~

!@ ("!Q!L 'AL+W=O&0P !", 8 M " @0$B !X;"]W;W)K&PO=V]R:W-H965T M&UL4$L! A0#% @ V(*365RIK/B_"@ !#< !@ M ("!OC 'AL+W=O&PO=V]R:W-H965T&UL4$L! M A0#% @ V(*3653]HGDX" J", !D ("!KT 'AL M+W=O20 >&PO=V]R:W-H965T&UL4$L! A0#% @ V(*3 M651N)Q,#"@ 6B !D ("!X'T 'AL+W=O&PO=V]R:W-H965T&UL4$L! A0#% @ V(*36<&PO=V]R:W-H965T&UL4$L! A0#% @ V(*367=))2P5%@ 5D\ !D M ("!>ZT 'AL+W=O&PO=V]R:W-H965T M&UL4$L! A0# M% @ V(*365=%%RZU" *!@ !D ("!B-X 'AL+W=O M&PO=V]R:W-H965T&UL4$L! A0#% @ V(*36\.R\' 1$@ &0 M @('$"0$ >&PO=V]R:W-H965T&UL4$L! A0#% @ V(*364&H?.2N" NQD !D M ("!(!4! 'AL+W=O&PO M=V]R:W-H965T&UL4$L! A0#% @ V(*366QY4H^^ @ "08 !D ("! M?5$! 'AL+W=O&PO=V]R:W-H965T&UL4$L! A0#% M @ V(*361\H4X!H P L < !D ("!&F ! 'AL+W=O&UL4$L! A0#% @ V(*360BF1WU* M P PP< !D ("!'6H! 'AL+W=O;0$ >&PO=V]R:W-H965T&UL4$L! A0#% @ V(*363FR_VH0! E D !D M ("!E'4! 'AL+W=O0$ >&PO=V]R M:W-H965T&UL M4$L! A0#% @ V(*368:/;B^= P > \ !D ("!F8,! M 'AL+W=O&PO=V]R:W-H965T&UL4$L! A0#% @ MV(*369DQH9:^" "D0 !D ("!U(\! 'AL+W=O&PO=V]R:W-H965T&UL4$L! 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Data and content created by government employees within the scope of their employment are not subject to domestic copyright protection. 17 U.S.C. 105. var Show= {};Show.LastAR=null,Show.showAR=function(a,r,w){if(Show.LastAR)Show.hideAR();var e=a;while(e&&e.nodeName!='TABLE')e=e.nextSibling;if(!e||e.nodeName!='TABLE') {var ref=((window)?w.document:document).getElementById(r);if(ref){e=ref.cloneNode(!0); e.removeAttribute('id');a.parentNode.appendChild(e)}} if(e)e.style.display='block';Show.LastAR=e};Show.hideAR=function(){Show.LastAR.style.display='none'};Show.toggleNext=function(a){var e=a;while(e.nodeName!='DIV')e=e.nextSibling;if(!e.style){}else if(!e.style.display){}else{var d,p_;if(e.style.display=='none'){d='block';p='-'}else{d='none';p='+'} e.style.display=d;if(a.textContent){a.textContent=p+a.textContent.substring(1)}else{a.innerText=p+a.innerText.substring(1)}}} XML 114 report.css IDEA: XBRL DOCUMENT /* Updated 2009-11-04 */ /* v2.2.0.24 */ /* DefRef Styles */ .report table.authRefData{ background-color: #def; border: 2px solid #2F4497; font-size: 1em; position: absolute; } .report table.authRefData a { display: block; font-weight: bold; } .report table.authRefData p { margin-top: 0px; } .report table.authRefData .hide { background-color: #2F4497; padding: 1px 3px 0px 0px; text-align: right; } .report table.authRefData .hide a:hover { background-color: #2F4497; } .report table.authRefData .body { height: 150px; overflow: auto; width: 400px; } .report table.authRefData table{ font-size: 1em; } /* Report Styles */ .pl a, .pl a:visited { color: black; text-decoration: none; } /* table */ .report { background-color: white; border: 2px solid #acf; clear: both; color: black; font: normal 8pt Helvetica, Arial, san-serif; margin-bottom: 2em; } .report hr { border: 1px solid #acf; } /* Top labels */ .report th { background-color: #acf; color: black; font-weight: bold; text-align: center; } .report th.void { background-color: transparent; color: #000000; font: bold 10pt Helvetica, Arial, san-serif; text-align: left; } .report .pl { text-align: left; vertical-align: top; white-space: normal; width: 200px; white-space: normal; /* word-wrap: break-word; */ } .report td.pl a.a { cursor: pointer; display: block; width: 200px; overflow: hidden; } .report td.pl div.a { width: 200px; } .report td.pl a:hover { background-color: #ffc; } /* Header rows... */ .report tr.rh { background-color: #acf; color: black; font-weight: bold; } /* Calendars... */ .report .rc { background-color: #f0f0f0; } /* Even rows... */ .report .re, .report .reu { background-color: #def; } .report .reu td { border-bottom: 1px solid black; } /* Odd rows... */ .report .ro, .report .rou { background-color: white; } .report .rou td { border-bottom: 1px solid black; } .report .rou table td, .report .reu table td { border-bottom: 0px solid black; } /* styles for footnote marker */ .report .fn { white-space: nowrap; } /* styles for numeric types */ .report .num, .report .nump { text-align: right; white-space: nowrap; } .report .nump { padding-left: 2em; } .report .nump { padding: 0px 0.4em 0px 2em; } /* styles for text types */ .report .text { text-align: left; white-space: normal; } .report .text .big { margin-bottom: 1em; width: 17em; } .report .text .more { display: none; } .report .text .note { font-style: italic; font-weight: bold; } .report .text .small { width: 10em; } .report sup { font-style: italic; } .report .outerFootnotes { font-size: 1em; } XML 116 FilingSummary.xml IDEA: XBRL DOCUMENT 3.24.4 html3315421true1450false8 falsefalseR1.htm100000 - Document - Document and Entity InformationSheethttp://engene.com/20241031/taxonomy/role/DocumentDocumentAndEntityInformationDocument and Entity InformationCover1 falsefalseR2.htm100010 - Statement - CONSOLIDATED BALANCE SHEETSSheethttp://engene.com/20241031/taxonomy/role/StatementConsolidatedBalanceSheets1CONSOLIDATED BALANCE SHEETSStatements2 falsefalseR3.htm100030 - Statement - CONSOLIDATED BALANCE SHEETS (Parenthetical)Sheethttp://engene.com/20241031/taxonomy/role/StatementConsolidatedBalanceSheetsParentheticalCONSOLIDATED BALANCE SHEETS (Parenthetical)Statements3 falsefalseR4.htm100050 - Statement - CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSSSheethttp://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementsOfOperationsAndComprehensiveLossCONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSSStatements4 falsefalseR5.htm100060 - Statement - CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)Sheethttp://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementsOfRedeemableConvertiblePreferredSharesAndShareholdersEquityDeficit1CONSO STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)Statements5 falsefalseR6.htm100070 - 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Disclosure - Leases - Summary of Cash Paid for Amounts Included in the Measurement of the Operating Lease Liabilities (Details)", "shortName": "Leases - Summary of Cash Paid for Amounts Included in the Measurement of the Operating Lease Liabilities (Details)", "isDefault": "false", "groupType": "disclosure", "subGroupType": "details", "menuCat": "Details", "order": "82", "firstAnchor": { "contextRef": "C_b40eff9d-4a78-4304-b7bd-1d3cf7fd35a1", "name": "us-gaap:OperatingLeasePayments", "unitRef": "U_USD", "xsiNil": "false", "lang": null, "decimals": "-3", "ancestors": ["span", "p", "td", "tr", "table", "engn:SummaryOfCashPaidForAmountsIncludedInMeasurementOfOperatingLeaseLiabilitiesTableTextBlock", "div", "ix:continuation", "div", "body", "html"], "reportCount": 1, "baseRef": "engn-20241031.htm", "first": true, "unique": true }, "uniqueAnchor": { "contextRef": "C_b40eff9d-4a78-4304-b7bd-1d3cf7fd35a1", "name": "us-gaap:OperatingLeasePayments", "unitRef": "U_USD", "xsiNil": "false", "lang": null, "decimals": "-3", "ancestors": ["span", "p", "td", "tr", "table", "engn:SummaryOfCashPaidForAmountsIncludedInMeasurementOfOperatingLeaseLiabilitiesTableTextBlock", "div", "ix:continuation", "div", "body", "html"], "reportCount": 1, "baseRef": "engn-20241031.htm", "first": true, "unique": true } }, "R83": { "role": "http://engene.com/20241031/taxonomy/role/DisclosureLeasesScheduleOfMaturitiesOfOperatingLeaseLiabilitiesDetails", "longName": "996225 - 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Disclosure - Related Party Transactions - Additional Information (Details)", "shortName": "Related Party Transactions - Additional Information (Details)", "isDefault": "false", "groupType": "disclosure", "subGroupType": "details", "menuCat": "Details", "order": "84", "firstAnchor": { "contextRef": "C_85049faf-612f-4e4e-ad55-1e1cae4c39e0", "name": "engn:ConvertibleDebenturesAndWarrants", "unitRef": "U_USD", "xsiNil": "false", "lang": null, "decimals": "-5", "ancestors": ["span", "p", "us-gaap:RelatedPartyTransactionsDisclosureTextBlock", "div", "body", "html"], "reportCount": 1, "baseRef": "engn-20241031.htm", "first": true, "unique": true }, "uniqueAnchor": { "contextRef": "C_85049faf-612f-4e4e-ad55-1e1cae4c39e0", "name": "engn:ConvertibleDebenturesAndWarrants", "unitRef": "U_USD", "xsiNil": "false", "lang": null, "decimals": "-5", "ancestors": ["span", "p", "us-gaap:RelatedPartyTransactionsDisclosureTextBlock", "div", "body", "html"], "reportCount": 1, "baseRef": "engn-20241031.htm", "first": true, "unique": true } }, "R85": { "role": "http://engene.com/20241031/taxonomy/role/DisclosureSubsequentEventsAdditionalInformationDetails", "longName": "996245 - Disclosure - Subsequent Events - Additional Information (Details)", "shortName": "Subsequent Events - Additional Information (Details)", "isDefault": "false", "groupType": "disclosure", "subGroupType": "details", "menuCat": "Details", "order": "85", "firstAnchor": { "contextRef": "C_63cb5bdd-ef69-4d3d-aa30-c127c512e35a", "name": "us-gaap:LineOfCreditFacilityMaximumBorrowingCapacity", "unitRef": "U_USD", "xsiNil": "false", "lang": null, "decimals": "INF", "ancestors": ["span", "p", "us-gaap:SubsequentEventsTextBlock", "div", "body", "html"], "reportCount": 1, "baseRef": "engn-20241031.htm", "first": true, "unique": true }, "uniqueAnchor": { "contextRef": "C_63cb5bdd-ef69-4d3d-aa30-c127c512e35a", "name": "us-gaap:LineOfCreditFacilityMaximumBorrowingCapacity", "unitRef": "U_USD", "xsiNil": "false", "lang": null, "decimals": "INF", "ancestors": ["span", "p", "us-gaap:SubsequentEventsTextBlock", "div", "body", "html"], "reportCount": 1, "baseRef": "engn-20241031.htm", "first": true, "unique": true } } }, "tag": { "us-gaap_AccountingPoliciesAbstract": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccountingPoliciesAbstract", "lang": { "en-us": { "role": { "label": "Accounting Policies [Abstract]" } } }, "auth_ref": [] }, "us-gaap_AccountingStandardsUpdate201613Member": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccountingStandardsUpdate201613Member", "presentation": ["http://engene.com/20241031/taxonomy/role/SummaryOfSignificantAccountingPoliciesAdditionalInformationDetail"], "lang": { "en-us": { "role": { "label": "Accounting Standards Update 2016-13 [Member]", "terseLabel": "ASU 2016-13", "documentation": "Accounting Standards Update 2016-13 Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." } } }, "auth_ref": ["r310"] }, "us-gaap_AccountingStandardsUpdate201912Member": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccountingStandardsUpdate201912Member", "presentation": ["http://engene.com/20241031/taxonomy/role/SummaryOfSignificantAccountingPoliciesAdditionalInformationDetail"], "lang": { "en-us": { "role": { "terseLabel": "ASU-2019-12", "label": "Accounting Standards Update 2019-12 [Member]", "documentation": "Accounting Standards Update 2019-12 Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes." } } }, "auth_ref": ["r507", "r508"] }, "us-gaap_AccountingStandardsUpdate202006Member": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccountingStandardsUpdate202006Member", "presentation": ["http://engene.com/20241031/taxonomy/role/SummaryOfSignificantAccountingPoliciesAdditionalInformationDetail"], "lang": { "en-us": { "role": { "terseLabel": "ASU 2020-06", "label": "Accounting Standards Update 2020-06 [Member]", "documentation": "Accounting Standards Update 2020-06 Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity." } } }, "auth_ref": ["r558", "r559", "r560", "r561", "r562", "r563", "r564", "r565", "r566", "r567", "r568"] }, "us-gaap_AccountsPayableAndAccruedLiabilitiesDisclosureTextBlock": { "xbrltype": "textBlockItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccountsPayableAndAccruedLiabilitiesDisclosureTextBlock", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureAccruedExpensesAndOtherCurrentLiabilities"], "lang": { "en-us": { "role": { "verboseLabel": "Accrued Expenses and Other Current Liabilities", "label": "Accounts Payable and Accrued Liabilities Disclosure [Text Block]", "documentation": "The entire disclosure for accounts payable and accrued liabilities at the end of the reporting period." } } }, "auth_ref": ["r75", "r78", "r83", "r1167"] }, "us-gaap_AccountsPayableCurrent": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccountsPayableCurrent", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedBalanceSheets1"], "lang": { "en-us": { "role": { "terseLabel": "Accounts payable", "label": "Accounts Payable, Current", "totalLabel": "Accounts Payable, Current, Total", "documentation": "Carrying value as of the balance sheet date of liabilities incurred (and for which invoices have typically been received) and payable to vendors for goods and services received that are used in an entity's business. Used to reflect the current portion of the liabilities (due within one year or within the normal operating cycle if longer)." } } }, "auth_ref": ["r75", "r936"] }, "engn_AccruedFinancingCosts": { "xbrltype": "monetaryItemType", "nsuri": "http://engene.com/20241031", "localname": "AccruedFinancingCosts", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureAccruedExpensesAndOtherCurrentLiabilitiesSummaryOfAccruedExpensesAndOtherCurrentLiabilitiesDetails"], "lang": { "en-us": { "role": { "terseLabel": "Accrued financing costs", "documentation": "Accrued financing costs.", "label": "Accrued Financing Costs" } } }, "auth_ref": [] }, "us-gaap_AccruedIncomeTaxesCurrent": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccruedIncomeTaxesCurrent", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureAccruedExpensesAndOtherCurrentLiabilitiesSummaryOfAccruedExpensesAndOtherCurrentLiabilitiesDetails"], "lang": { "en-us": { "role": { "terseLabel": "Accrued income tax payable", "label": "Accrued Income Taxes, Current", "documentation": "Carrying amount as of the balance sheet date of the unpaid sum of the known and estimated amounts payable to satisfy all currently due domestic and foreign income tax obligations." } } }, "auth_ref": ["r78", "r136"] }, "engn_AccruedInterestReceivableWrittenOff": { "xbrltype": "monetaryItemType", "nsuri": "http://engene.com/20241031", "localname": "AccruedInterestReceivableWrittenOff", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureMarketableSecuritiesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "documentation": "Accrued interest receivable written off.", "label": "Accrued Interest Receivable Written Off", "terseLabel": "Accrued interest receivable written off" } } }, "auth_ref": [] }, "us-gaap_AccruedLiabilitiesAndOtherLiabilities": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccruedLiabilitiesAndOtherLiabilities", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureAccruedExpensesAndOtherCurrentLiabilitiesSummaryOfAccruedExpensesAndOtherCurrentLiabilitiesDetails", "http://engene.com/20241031/taxonomy/role/StatementConsolidatedBalanceSheets1"], "lang": { "en-us": { "role": { "totalLabel": "Total accrued expenses and other current liabilities", "terseLabel": "Accrued expenses and other current liabilities", "label": "Accrued Liabilities and Other Liabilities", "documentation": "Amount of expenses incurred but not yet paid nor invoiced, and liabilities classified as other." } } }, "auth_ref": [] }, "us-gaap_AccruedProfessionalFeesCurrent": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccruedProfessionalFeesCurrent", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureAccruedExpensesAndOtherCurrentLiabilitiesSummaryOfAccruedExpensesAndOtherCurrentLiabilitiesDetails"], "lang": { "en-us": { "role": { "terseLabel": "Professional fees", "label": "Accrued Professional Fees, Current", "documentation": "Carrying value as of the balance sheet date of obligations incurred through that date and payable for professional fees, such as for legal and accounting services received. Used to reflect the current portion of the liabilities (due within one year or within the normal operating cycle if longer)." } } }, "auth_ref": ["r78"] }, "engn_AccruedResearchAndDevelopmentExpenseCurrent": { "xbrltype": "monetaryItemType", "nsuri": "http://engene.com/20241031", "localname": "AccruedResearchAndDevelopmentExpenseCurrent", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureAccruedExpensesAndOtherCurrentLiabilitiesSummaryOfAccruedExpensesAndOtherCurrentLiabilitiesDetails"], "lang": { "en-us": { "role": { "terseLabel": "Accrued research and development expenses", "label": "Accrued Research And Development Expense Current", "documentation": "Accrued research and development expenses current." } } }, "auth_ref": [] }, "us-gaap_AccumulatedDepreciationDepletionAndAmortizationPropertyPlantAndEquipment": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccumulatedDepreciationDepletionAndAmortizationPropertyPlantAndEquipment", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosurePropertyAndEquipmentNetSummaryOfPropertyAndEquipmentDetails"], "lang": { "en-us": { "role": { "terseLabel": "Less: Accumulated depreciation and amortization", "label": "Accumulated Depreciation, Depletion and Amortization, Property, Plant, and Equipment", "periodEndLabel": "Accumulated Depreciation, Depletion and Amortization, Property, Plant, and Equipment, Ending Balance", "periodStartLabel": "Accumulated Depreciation, Depletion and Amortization, Property, Plant, and Equipment, Beginning Balance", "totalLabel": "Accumulated Depreciation, Depletion and Amortization, Property, Plant, and

~~Equipment, Total", "documentation": "Amount of accumulated depreciation, depletion and amortization for physical assets used in the normal conduct of business to produce goods and services." } } }, "auth_ref": ["r40", "r175", "r733"] }, "us-gaap_AccumulatedOtherComprehensiveIncomeLossNetOfTax": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccumulatedOtherComprehensiveIncomeLossNetOfTax", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedBalanceSheets1"], "lang": { "en-us": { "role": { "terseLabel": "Accumulated other comprehensive loss", "label": "Accumulated Other Comprehensive Income (Loss), Net of Tax", "totalLabel": "Accumulated Other Comprehensive Income (Loss), Net of Tax, Total", "documentation": "Amount, after tax, of accumulated increase (decrease) in equity from transaction and other event and circumstance from nonowner source." } } }, "auth_ref": ["r22", "r23", "r96", "r183", "r728", "r755", "r759"] }, "us-gaap_AccumulatedOtherComprehensiveIncomeMember": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AccumulatedOtherComprehensiveIncomeMember", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementsOfRedeemableConvertiblePreferredSharesAndShareholdersEquityDeficit1"], "lang": { "en-us": { "role": { "terseLabel": "Accumulated Other Comprehensive Loss", "label": "AOCI Attributable to Parent [Member]", "documentation": "Accumulated increase (decrease) in equity from transactions and other events and circumstances from non-owner sources, attributable to the parent. Excludes net income (loss), and accumulated changes in equity from transactions resulting from investments by owners and distributions to owners." } } }, "auth_ref": ["r6", "r15", "r23", "r550", "r553", "r634", "r750", "r751", "r1091", "r1092", "r1093", "r1105", "r1106", "r1107", "r1108"] }, "engn_AcquirerAxis": { "xbrltype": "stringItemType", "nsuri": "http://engene.com/20241031", "localname": "AcquirerAxis", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureCommonSharesAdditionalInformationDetails", "http://engene.com/20241031/taxonomy/role/DisclosureReverseRecapitalizationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "documentation": "Acquirer.", "label": "Acquirer [Axis]" } } }, "auth_ref": [] }, "engn_AcquirerDomain": { "xbrltype": "domainItemType", "nsuri": "http://engene.com/20241031", "localname": "AcquirerDomain", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureCommonSharesAdditionalInformationDetails", "http://engene.com/20241031/taxonomy/role/DisclosureReverseRecapitalizationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "documentation": "Acquirer.", "label": "Acquirer [Domain]" } } }, "auth_ref": [] }, "ecd_Additional402vDisclosureTextBlock": { "xbrltype": "textBlockItemType", "nsuri": "http://xbrl.sec.gov/ecd/2024", "localname": "Additional402vDisclosureTextBlock", "presentation": ["http://xbrl.sec.gov/ecd/role/PvpDisclosure"], "lang": { "en-us": { "role": { "label": "Additional 402(v) Disclosure [Text Block]", "terseLabel": "Additional 402(v) Disclosure" } } }, "auth_ref": ["r1010"] }, "engn_AdditionalAwardsApprovedForIssuance": { "xbrltype": "sharesItemType", "nsuri": "http://engene.com/20241031", "localname": "AdditionalAwardsApprovedForIssuance", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Additional awards approved for issuance", "label": "Additional Awards Approved For Issuance", "documentation": "Additional awards approved for issuance." } } }, "auth_ref": [] }, "us-gaap_AdditionalPaidInCapitalCommonStock": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AdditionalPaidInCapitalCommonStock", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedBalanceSheets1"], "lang": { "en-us": { "role": { "terseLabel": "Additional paid-in capital", "label": "Additional Paid in Capital, Common Stock", "documentation": "Value received from shareholders in common stock-related transactions that are in excess of par value or stated value and amounts received from other stock-related transactions. Includes only common stock transactions (excludes preferred stock transactions). May be called contributed capital, capital in excess of par, capital surplus, or paid-in capital." } } }, "auth_ref": ["r91"] }, "us-gaap_AdditionalPaidInCapitalMember": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "AdditionalPaidInCapitalMember", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementsOfRedeemableConvertiblePreferredSharesAndShareholdersEquityDeficit1"], "lang": { "en-us": { "role": { "terseLabel": "Additional Paid in Capital", "label": "Additional Paid-in Capital [Member]", "documentation": "Excess of issue price over par or stated value of the entity's capital stock and amounts received from other transactions involving the entity's stock or stockholders." } } }, "auth_ref": ["r773", "r1105", "r1106", "r1107", "r1108", "r1179", "r1255"] }, "engn_AdditionalReservesOfCommonStockForIssuance": { "xbrltype": "sharesItemType", "nsuri": "http://engene.com/20241031", "localname": 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Business description describes the nature and type of organization including but not limited to organizational structure as may be applicable to holding companies, parent and subsidiary relationships, business divisions, business units, business segments, affiliates and information about significant ownership of the reporting entity. Basis of presentation describes the underlying basis used to prepare the financial statements (for example, US Generally Accepted Accounting Principles, Other Comprehensive Basis of Accounting, IFRS)." } } }, "auth_ref": ["r74", "r110", "r111"] }, "country_CA": { "xbrltype": "domainItemType", "nsuri": "http://xbrl.sec.gov/country/2024", "localname": "CA", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "CANADA", "terseLabel": "Canadian" } } }, "auth_ref": [] }, "us-gaap_CapitalExpendituresIncurredButNotYetPaid": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "CapitalExpendituresIncurredButNotYetPaid", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementOfCashFlows"], "lang": { "en-us": { "role": { "terseLabel": "Fixed assets included in accrued expenses and accounts payable", "label": "Capital Expenditures Incurred but Not yet Paid", "documentation": "Future cash outflow to pay for purchases of fixed assets that have occurred." } } }, "auth_ref": ["r30", "r31", "r32"] }, "engn_CapitalLossCarryforward": { "xbrltype": "monetaryItemType", "nsuri": "http://engene.com/20241031", "localname": "CapitalLossCarryforward", "crdr": "debit", "presentation": [

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Includes other kinds of accounts that have the general characteristics of demand deposits. Excludes cash and cash equivalents within disposal group and discontinued operation." } } }, "auth_ref": ["r149", "r724", "r784", "r807", "r936", "r959", "r1086"] }, "us-gaap_CashAndCashEquivalentsAtCarryingValue": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "CashAndCashEquivalentsAtCarryingValue", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedBalanceSheets1", "http://engene.com/20241031/taxonomy/role/SummaryOfSignificantAccountingPoliciesAdditionalInformationDetail"], "lang": { "en-us": { "role": { "terseLabel": "Cash and cash equivalents", "label": "Cash and Cash Equivalents, at Carrying Value", "totalLabel": "Cash and Cash Equivalents, at Carrying Value, Total", "documentation": "Amount of currency on hand as well as demand deposits with banks or financial institutions. Includes other kinds of accounts that have the general characteristics of demand deposits. Also includes short-term, highly liquid investments that are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates. 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Other information that may be disclosed includes (1) the nature of any restrictions on the entity's use of its cash and cash equivalents, (2) whether the entity's cash and cash equivalents are insured or expose the entity to credit risk, (3) the classification of any negative balance accounts (overdrafts), and (4) the carrying basis of cash equivalents (for example, at cost) and whether the carrying amount of cash equivalents approximates fair value." } } }, "auth_ref": ["r29"] }, "us-gaap_CashCashEquivalentsRestrictedCashAndRestrictedCashEquivalentsIncludingDisposalGroupAndDiscontinuedOperations": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "CashCashEquivalentsRestrictedCashAndRestrictedCashEquivalentsIncludingDisposalGroupAndDiscontinuedOperations", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementOfCashFlows"], "lang": { "en-us": { "role": { "totalLabel": "Cash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents, Including Disposal Group and Discontinued Operations, Total", "label": "Cash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents, Including Disposal Group and Discontinued Operations", "periodEndLabel": "Cash and cash equivalents at end of period", "periodStartLabel": "Cash and cash equivalents at beginning of period", "documentation": "Amount of cash and cash equivalents, and cash and cash equivalents restricted to withdrawal or usage; including, but not limited to, disposal group and discontinued operations. Cash includes, but is not limited to, currency on hand, demand deposits with banks or financial institutions, and other accounts with general characteristics of demand deposits. Cash equivalents include, but are not limited to, short-term, highly liquid investments that are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates." } } }, "auth_ref": ["r28", "r107", "r203"] }, "us-gaap_CashCashEquivalentsRestrictedCashAndRestrictedCashEquivalentsPeriodIncreaseDecreaseIncludingExchangeRateEffect": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "CashCashEquivalentsRestrictedCashAndRestrictedCashEquivalentsPeriodIncreaseDecreaseIncludingExchangeRateEffect", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementOfCashFlows"], "lang": { "en-us": { "role": { "totalLabel": "Net increase in cash and cash equivalents", "label": "Cash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents, Period Increase (Decrease), Including Exchange Rate Effect", "documentation": "Amount of increase (decrease) in cash, cash equivalents, and cash and cash equivalents restricted to withdrawal or usage; including effect from exchange rate change. 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"http://engene.com/20241031/taxonomy/role/DisclosureFairValueMeasurementsSummaryOfChangeInEstimatedFairValueOfWarrantLiabilitiesDetails",
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purchase securities (usually equity) from the issuer at a specific price within a certain time frame. Warrants are often included in a new debt issue to entice investors by a
higher return potential. The main difference between warrants and call options is that warrants are issued and guaranteed by the company, whereas options are exchange
instruments and are not issued by the company. Also, the lifetime of a warrant is often measured in years, while the lifetime of a typical option is measured in months." } } },
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been sold or granted to shareholders (includes common shares that were issued, repurchased and remain in the treasury). These shares represent capital invested by the
firm's shareholders and owners, and may be all or only a portion of the number of shares authorized. Shares issued include shares outstanding and shares held in the
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information about the (shared) activity, region or economic characteristic that identifies the concentration, (2) the face or contract amount of the instrument, (3) the nature
and terms of the instrument, including the market risk, cash requirements and accounting policies for it, (4) the maximum amount of loss due to credit risk that would be
incurred if the counterparties failed completely to perform according to the terms of the contracts, and any security or collateral that proved to be of no value, (5) the entity's
policy of requiring collateral or other security to support financial instruments subject to credit risk, information about access to collateral or other security, and a brief
description of the security supporting those financial instruments, and (6) the policy of entering into and a brief description of master netting arrangements to mitigate the
credit risk, and the extent to which such arrangements would reduce the maximum amount of loss due to credit risk." } } }, "auth_ref": ["r73", "r132"] },
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Interest and Unamortized Deferred Financing Costs of Convertible Debentures Recorded on Balance Sheet", "documentation": "Tabular disclosure of convertible debt
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Total", "documentation": "Amount of current federal, state, and local tax expense (benefit) attributable to income (loss) from continuing operations. Includes, but is not
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underlying arrangements, rationale for a classification as long-term, including repayment terms, interest rates, collateral provided, restrictions on use of assets and activities,
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"http://engene.com/20241031/taxonomy/role/DisclosureNotesPayableScheduleOfEstimatedFuturePrincipalPaymentsDueUnderTheLoanAgreementDetails", "http://engene.com/20241031/taxonomy/role/DisclosureRelatedPartyTransactionsAdditionalInformationDetails", "http://engene.com/20241031/taxonomy/role/DisclosureSubsequentEventsAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Debt Instrument, Name [Domain]", "documentation": "The name for the particular debt instrument or borrowing that distinguishes it from other debt instruments or borrowings, including draws against credit facilities." } } }, "auth_ref": ["r20", "r212", "r370", "r371", "r372", "r373", "r374", "r376", "r381", "r382", "r383", "r384", "r386", "r387", "r388", "r389", "r390", "r391", "r904", "r905", "r906", "r907", "r908", "r934", "r1101", "r1127", "r1128", "r1129", "r1200", "r1202"] }, "us-gaap_DebtInstrumentRepaidPrincipal": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", 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Includes, but is not limited to, debt issuance costs, the effects of refinancings, method of amortizing debt issuance costs and original issue discount, and classifications of debt." } } }, "auth_ref": ["r13"] }, "us-gaap_DebtSecuritiesAvailableForSaleAccruedInterestAfterAllowanceForCreditLoss": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "DebtSecuritiesAvailableForSaleAccruedInterestAfterAllowanceForCreditLoss", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureMarketableSecuritiesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "totalLabel": "Debt Securities, Available-for-Sale, Accrued Interest, after Allowance for Credit Loss, Total", "label": "Debt Securities, Available-for-Sale, Accrued Interest, after Allowance for Credit Loss", "terseLabel": "Accrued interest receivable", "documentation": "Amount, after allowance for credit loss, of accrued interest on investment in debt security measured at fair value with change in fair value recognized in other comprehensive income (available-for-sale)." } } }, "auth_ref": ["r285", "r328", "r329", "r330"] }, "us-gaap_DebtSecuritiesAvailableForSaleAccruedInterestAfterAllowanceForCreditLossStatementOfFinancialPositionExtensibleList": { "xbrltype": "enumerationSetItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "DebtSecuritiesAvailableForSaleAccruedInterestAfterAllowanceForCreditLossStatementOfFinancialPositionExtensibleList", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureMarketableSecuritiesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Debt Securities, Available-for-Sale, Accrued Interest, after Allowance for Credit Loss, Statement of Financial Position [Extensible Enumeration]", "documentation": "Indicates line item in statement of financial position that includes accrued interest, after allowance for credit loss, on investment in debt security measured at fair value with change in fair value recognized in other comprehensive income (available-for-sale)." } } }, "auth_ref": ["r329"] }, "us-gaap_DebtSecuritiesAvailableForSaleContinuousUnrealizedLossPositionLessThan12MonthsNumberOfPositions": { "xbrltype": "integerItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "DebtSecuritiesAvailableForSaleContinuousUnrealizedLossPositionLessThan12MonthsNumberOfPositions", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureMarketableSecuritiesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Debt Securities, Available-for-Sale, Continuous Unrealized Loss Position, Less than 12 Months, Number of Positions", "terseLabel": "Number of unrealized loss position", "documentation": "Number of investments in debt securities measured at fair value with change in fair value recognized in other comprehensive income (available-for-sale), in continuous unrealized loss position for less than 12 months, without an allowance for credit loss. Includes beneficial interest in securitized financial asset." } } }, "auth_ref": ["r1123"] }, "us-gaap_DebtSecuritiesAvailableForSaleRealizedGainLoss": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "DebtSecuritiesAvailableForSaleRealizedGainLoss", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureMarketableSecuritiesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "totalLabel": "Debt Securities, Available-for-Sale, Realized Gain (Loss), Total", "label": "Debt Securities, Available-for-Sale, Realized Gain (Loss)", "terseLabel": "Realized gains or losses on sale or maturity of available-for-sale securities", "documentation": "Amount of realized gain (loss) on investment in debt security measured at fair value with change in fair value recognized in other comprehensive income (available-for-sale)." } } }, "auth_ref": ["r1118"] }, "us-gaap_DebtSecuritiesAvailableForSaleUnrealizedLossPosition": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "DebtSecuritiesAvailableForSaleUnrealizedLossPosition", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureMarketableSecuritiesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "totalLabel": "Debt Securities, Available-for-Sale, Unrealized Loss Position, Total", "label": "Debt Securities, Available-for-Sale, Unrealized Loss Position", "terseLabel": "Credit losses", "documentation": "Amount of investment in debt security measured at fair value with change in fair value recognized in other comprehensive income (available-for-sale), in unrealized loss position without allowance for credit loss." } } }, "auth_ref": ["r145", "r332", "r902"] }, "engn_DebtSecuritiesUnrealizedLosses": { "xbrltype": "percentItemType", "nsuri": "http://engene.com/20241031", "localname": "DebtSecuritiesUnrealizedLosses", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureMarketableSecuritiesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "documentation": "Debt securities unrealized losses.", "label": "Debt Securities Unrealized Losses", "terseLabel": "Debt securities unrealized losses" } } }, "auth_ref": [] }, "us-gaap_DeferredCostsCurrentAndNoncurrent": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "DeferredCostsCurrentAndNoncurrent", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/SummaryOfSignificantAccountingPoliciesAdditionalInformationDetail"], "lang": { "en-us": { "role": { "terseLabel": "Deferred transaction costs", "label": "Deferred Costs", "totalLabel": "Deferred Costs, Total", "documentation": "The carrying amount of deferred costs." } } }, "auth_ref": [] }, "us-gaap_DeferredFederalStateAndLocalTaxExpenseBenefit": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "DeferredFederalStateAndLocalTaxExpenseBenefit", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesSummaryOfComponentsOfTheProvisionForRecoveryOfIncomeTaxesDetails"], "lang": { "en-us": { "role": { "terseLabel": "Domestic (Canada)", "label": "Deferred Federal, State and Local, Tax Expense (Benefit)", "totalLabel": "Deferred Federal, State and Local, Tax Expense (Benefit), Total", "documentation": "Amount of deferred federal, state, and local tax expense (benefit) attributable to income (loss) from continuing operations. Includes, but is not limited to, deferred national, regional, territorial, and provincial tax expense (benefit) for non-US (United States of America) jurisdiction." } } }, "auth_ref": ["r1168"] }, "us-gaap_DeferredFinanceCostsNet": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "DeferredFinanceCostsNet", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureConvertibleDebenturesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Debt issuance costs", "label": "Debt Issuance Costs, Net", "totalLabel": "Debt Issuance Costs, Net, Total", "documentation": "Amount, after accumulated amortization, of debt issuance costs. Includes, but is not limited to, legal, accounting, underwriting, printing, and registration costs." } } }, "auth_ref": ["r1137", "r1199", "r1200", "r1202"] }, "engn_DeferredFinancingCostCurrent": { "xbrltype": "monetaryItemType", "nsuri": "http://engene.com/20241031", "localname": "DeferredFinancingCostCurrent", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedBalanceSheets1"], "lang": { "en-us": { "role": { "documentation": "Deferred financing cost current.", "label": "Deferred Financing Cost Current", "terseLabel": "Deferred financing cost" } } }, "auth_ref": [] }, "us-gaap_DeferredForeignIncomeTaxExpenseBenefit": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "DeferredForeignIncomeTaxExpenseBenefit", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesSummaryOfComponentsOfTheProvisionForRecoveryOfIncomeTaxesDetails"], "lang": { "en-us": { "role": { 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Includes, but is not limited to, national jurisdiction for non-U.S. jurisdiction." } } }, "auth_ref": ["r483"] }, "ecd_DvddsOrOthrErngsPdOnEqtyAwrdsNtOthrwsRflctdInTtlCompForCvrdYrMember": { "xbrltype": "domainItemType", "nsuri": "http://xbrl.sec.gov/ecd/2024", "localname": "DvddsOrOthrErngsPdOnEqtyAwrdsNtOthrwsRflctdInTtlCompForCvrdYrMember", "presentation": ["http://xbrl.sec.gov/ecd/role/PvpDisclosure"], "lang": { "en-us": { "role": { "label": "Dividends or Other Earnings Paid on Equity Awards not Otherwise Reflected in Total Compensation for Covered Year [Member]", "terseLabel": "Dividends or Other Earnings Paid on Equity Awards not Otherwise Reflected in Total Compensation for Covered Year" } } }, "auth_ref": ["r1020"] }, "us-gaap_EarliestTaxYearMember": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EarliestTaxYearMember", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Earliest Tax Year", "terseLabel": "2028", "documentation": "Earliest identified tax year." } } }, "auth_ref": ["r1172"] }, "us-gaap_EarningsPerShareAbstract": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EarningsPerShareAbstract", "lang": { "en-us": { "role": { "label": "Earnings Per Share [Abstract]" } } }, "auth_ref": [] }, "us-gaap_EarningsPerShareBasic": { "xbrltype": "perShareItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EarningsPerShareBasic", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureNetLossPerShareSummaryOfBasicAndDilutedNetLossPerShareDetails", "http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementsOfOperationsAndComprehensiveLoss"], "lang": { "en-us": { "role": { "totalLabel": "Earnings Per Share, Basic, Total", "label": "Earnings Per Share, Basic", "terseLabel": "Net loss per share of common shares, basic", "documentation": "The amount of net income (loss) for the period per each share of common stock or unit outstanding during the reporting period." } } }, "auth_ref": ["r195", "r221", "r222", "r223", "r224", "r225", "r226", "r233", "r236", "r244", "r245", "r246", "r251", "r525", "r535", "r567", "r568", "r716", "r742", "r893"] }, "us-gaap_EarningsPerShareDiluted": { "xbrltype": "perShareItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EarningsPerShareDiluted", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureNetLossPerShareSummaryOfBasicAndDilutedNetLossPerShareDetails", "http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementsOfOperationsAndComprehensiveLoss"], "lang": { "en-us": { "role": { "totalLabel": "Earnings Per Share, Diluted, Total", "label": "Earnings Per Share, Diluted", "terseLabel": "Net loss per share of common shares, diluted", "documentation": "The amount of net income (loss) for the period available to each share of common stock or common unit outstanding during the reporting period and to each share or unit that would have been outstanding assuming the issuance of common shares or units for all dilutive potential common shares or units outstanding during the reporting period." } } }, "auth_ref": ["r195", "r221", "r222", "r223", "r224", "r225", "r226", "r236", "r244", "r245", "r246", "r251", "r525", "r535", "r567", "r568", "r716", "r742", "r893"] }, "us-gaap_EarningsPerSharePolicyTextBlock": { "xbrltype": "textBlockItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EarningsPerSharePolicyTextBlock", "presentation": ["http://engene.com/20241031/taxonomy/role/SummaryOfSignificantAccountingPoliciesPolicies"], "lang": { "en-us": { "role": { "terseLabel": "Net Loss Per Share", "label": "Earnings Per Share, Policy [Policy Text Block]", "documentation": "Disclosure of accounting policy for computing basic and diluted earnings or loss per share for each class of common stock and participating security. Addresses all significant policy factors, including any antidilutive items that have been excluded from the computation and takes into account stock dividends, splits and reverse splits that occur after the balance sheet date of the latest reporting period but before the issuance of the financial statements." } } }, "auth_ref": ["r34", "r35", "r248"] }, "us-gaap_EarningsPerShareTextBlock": { "xbrltype": "textBlockItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EarningsPerShareTextBlock", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureNetLossPerShare"], "lang": { "en-us": { "role": { "terseLabel": "Net Loss Per Share", "label": "Earnings Per Share [Text Block]", "documentation": "The entire disclosure for earnings per share." } } }, "auth_ref": ["r232", "r247", "r249", "r250"] }, "us-gaap_EffectOfExchangeRateOnCashCashEquivalentsRestrictedCashAndRestrictedCashEquivalents": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EffectOfExchangeRateOnCashCashEquivalentsRestrictedCashAndRestrictedCashEquivalents", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementOfCashFlows"], "lang": { "en-us": { "role": { "label": "Effect of Exchange Rate on Cash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents, Continuing Operations", "terseLabel": "Effect of exchange rate changes on cash", "documentation": "Amount of increase (decrease) from effect of exchange rate changes on cash and cash equivalents, and cash and cash equivalents restricted to withdrawal or usage; held in foreign currencies. Excludes amounts for disposal group and discontinued operations. Cash includes, but is not limited to, currency on hand, demand deposits with banks or financial institutions, and other accounts with general characteristics of demand deposits. Cash equivalents include, but are not limited to, short-term, highly liquid investments that are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates." } } }, "auth_ref": ["r598"] }, "us-gaap_EffectiveIncomeTaxRateContinuingOperations": { "xbrltype": "percentItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EffectiveIncomeTaxRateContinuingOperations", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesSummaryOfReconciliationOfCompanysStatutoryIncomeTaxRateDetails"], "lang": { "en-us": { "role": { "totalLabel": "Effective income tax rate", "label": "Effective Income Tax Rate Reconciliation, Percent", "documentation": "Percentage of current income tax expense (benefit) and deferred income tax expense (benefit) pertaining to continuing operations." } } }, "auth_ref": ["r483", "r920"] }, 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Income Tax Rate Reconciliation, at Federal Statutory Income Tax Rate, Percent", "terseLabel": "Income at Canadian statutory rate", "documentation": "Percentage of domestic federal statutory tax rate applicable to pretax income (loss)." } } }, "auth_ref": ["r209", "r483", "r512", "r920"] }, "us-gaap_EffectiveIncomeTaxRateReconciliationChangeInDeferredTaxAssetsValuationAllowance": { "xbrltype": "percentItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EffectiveIncomeTaxRateReconciliationChangeInDeferredTaxAssetsValuationAllowance", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesSummaryOfReconciliationOfCompanysStatutoryIncomeTaxRateDetails"], "lang": { "en-us": { "role": { "terseLabel": "Valuation allowance", "label": "Effective Income Tax Rate Reconciliation, Change in Deferred Tax Assets Valuation Allowance, Percent", "documentation": "Percentage of the difference between reported income tax expense (benefit) and expected income tax 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federal statutory income tax rates to pretax income (loss) from continuing operations applicable to statutory income tax expense (benefit) outside of the country of domicile." } } }, "auth_ref": ["r484", "r487", "r920", "r1104", "r1169"] }, "us-gaap_EffectiveIncomeTaxRateReconciliationNondeductibleExpense": { "xbrltype": "percentItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EffectiveIncomeTaxRateReconciliationNondeductibleExpense", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesSummaryOfReconciliationOfCompanysStatutoryIncomeTaxRateDetails"], "lang": { "en-us": { "role": { "terseLabel": "Permanent differences", "label": "Effective Income Tax Rate Reconciliation, Nondeductible Expense, Percent", "totalLabel": "Effective Income Tax Rate Reconciliation, Nondeductible Expense, Percent, Total", "documentation": "Percentage of the difference between reported income tax expense (benefit) and expected income tax expense (benefit) computed by applying the domestic federal statutory income tax rates to pretax income (loss) from continuing operations attributable to nondeductible expenses." } } }, "auth_ref": ["r490", "r491", "r1104", "r1169"] }, "us-gaap_EffectiveIncomeTaxRateReconciliationOtherAdjustments": { "xbrltype": "percentItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EffectiveIncomeTaxRateReconciliationOtherAdjustments", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesSummaryOfReconciliationOfCompanysStatutoryIncomeTaxRateDetails"], "lang": { "en-us": { "role": { "terseLabel": "Other", "label": "Effective Income Tax Rate Reconciliation, Other Adjustments, Percent", "documentation": "Percentage of the difference between reported income tax expense (benefit) and expected income tax expense (benefit) computed by applying the domestic federal statutory income tax rates to pretax income (loss) from continuing operations attributable to other adjustments." } } }, 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"r1169"] }, "us-gaap_EffectiveIncomeTaxRateReconciliationTaxCredits": { "xbrltype": "percentItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EffectiveIncomeTaxRateReconciliationTaxCredits", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesSummaryOfReconciliationOfCompanysStatutoryIncomeTaxRateDetails"], "lang": { "en-us": { "role": { "terseLabel": "Tax credits", "label": "Effective Income Tax Rate Reconciliation, Tax Credit, Percent", "totalLabel": "Effective Income Tax Rate Reconciliation, Tax Credit, Percent, Total", "documentation": "Percentage of the difference between reported income tax expense (benefit) and expected income tax expense (benefit) computed by applying the domestic federal statutory income tax rates to pretax income (loss) from continuing operations attributable to tax credits. Including, but not limited to, research credit, foreign tax credit, investment tax credit, and other tax credits." } } }, "auth_ref": ["r488", "r491", "r1104", "r1169"] }, "us-gaap_EmbeddedDerivativeFairValueOfEmbeddedDerivativeLiability": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EmbeddedDerivativeFairValueOfEmbeddedDerivativeLiability", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureConvertibleDebenturesAdditionalInformationDetails", "http://engene.com/20241031/taxonomy/role/DisclosureFairValueMeasurementsAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Embedded derivative liability measured at fair value", "label": "Embedded Derivative, Fair Value of Embedded Derivative Liability", "documentation": "Fair value as of the balance sheet date of the embedded derivative or group of embedded derivatives classified as a liability." } } }, "auth_ref": ["r129", "r1183", "r1184", "r1185"] }, "us-gaap_EmbeddedDerivativeFinancialInstrumentsMember": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EmbeddedDerivativeFinancialInstrumentsMember", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureFairValueMeasurementsTables"], "lang": { "en-us": { "role": { "terseLabel": "Convertible Debentures Embedded Derivative Liabilities", "label": "Embedded Derivative Financial Instruments [Member]", "documentation": "Derivative instrument embedded in host contract." } } }, "auth_ref": [] }, "us-gaap_EmbeddedDerivativeLiabilityMeasurementInput": { "xbrltype": "decimalItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EmbeddedDerivativeLiabilityMeasurementInput", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureFairValueMeasurementsScheduleOfConvertibleDebenturesEmbeddedDerivativeLiabilitiesDetails"], "lang": { "en-us": { "role": { "verboseLabel": "Fair value using the quoted market price for FEAC's common share", "terseLabel": "Embedded derivative liability measurement input", "label": "Embedded Derivative Liability, Measurement Input", "documentation": "Value of input used to measure embedded derivative liability." } } }, "auth_ref": ["r572", "r573", "r574"] }, "engn_EmbeddedDerivativeLiabilityMeasurementTerm": { "xbrltype": "durationItemType", "nsuri": "http://engene.com/20241031", "localname": "EmbeddedDerivativeLiabilityMeasurementTerm", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureFairValueMeasurementsAdditionalInformationDetails"], "lang": { "en-us": { "role": { "documentation": "Embedded derivative liability measurement term.", "label": "Embedded Derivative Liability Measurement Term", "terseLabel": "Embedded derivative liability measurement term" } } }, "auth_ref": [] }, "us-gaap_EmbeddedDerivativeLossOnEmbeddedDerivative": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EmbeddedDerivativeLossOnEmbeddedDerivative", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureConvertibleDebenturesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Loss on extinguishment", "label": "Embedded Derivative, Loss on Embedded Derivative", "documentation": "Decrease in the fair value of the embedded derivative or group of embedded derivatives included in earnings in the period." } } }, "auth_ref": ["r1178"] }, "engn_EmployeeEntitledForContinuedPayAndHealthInsuranceBenefits": { "xbrltype": "durationItemType", "nsuri": "http://engene.com/20241031", "localname": "EmployeeEntitledForContinuedPayAndHealthInsuranceBenefits", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "documentation": "Employee entitled for continued pay and health insurance benefits.", "label": "Employee entitled for continued pay and health insurance benefits", "terseLabel": "Employee entitled for continued pay and health insurance benefits" } } }, "auth_ref": [] }, "us-gaap_EmployeeRelatedLiabilitiesCurrent": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EmployeeRelatedLiabilitiesCurrent", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureAccruedExpensesAndOtherCurrentLiabilitiesSummaryOfAccruedExpensesAndOtherCurrentLiabilitiesDetails"], "lang": { "en-us": { "role": { "verboseLabel": "Employee compensation and related benefits", "label": "Employee-related Liabilities, Current", "totalLabel": "Employee-related Liabilities, Current, Total", "documentation": "Total of the carrying values as of the balance sheet date of obligations incurred through that date and payable for obligations related to services received from employees, such as accrued salaries and bonuses, payroll taxes and fringe benefits. Used to reflect the current portion of the liabilities (due within one year or within the normal operating cycle if longer)." } } }, "auth_ref": ["r78"] }, "us-gaap_EmployeeServiceShareBasedCompensationNonvestedAwardsTotalCompensationCostNotYetRecognized": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EmployeeServiceShareBasedCompensationNonvestedAwardsTotalCompensationCostNotYetRecognized", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Unrecognized compensation expense", "label": "Share-Based Payment Arrangement, Nonvested Award, Cost Not yet Recognized, Amount", "totalLabel": "Share-Based Payment Arrangement, Nonvested Award, Cost Not yet Recognized, Amount, Total", "documentation": "Amount of cost not yet recognized for nonvested award under share-based payment arrangement." } } }, "auth_ref": ["r467"] }, "us-gaap_EmployeeServiceShareBasedCompensationNonvestedAwardsTotalCompensationCostNotYetRecognizedPeriodForRecognition1": { "xbrltype": "durationItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EmployeeServiceShareBasedCompensationNonvestedAwardsTotalCompensationCostNotYetRecognizedPeriodForRecognition1", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Unrecognized compensation expense weighted-average period of recognition", "label": "Share-Based Payment Arrangement, Nonvested Award, Cost Not yet Recognized, Period for

Recognition", "documentation": "Weighted-average period over which cost not yet recognized is expected to be recognized for award under share-based payment arrangement, in 'PnYnMnDTnHnMnS' format, for example, 'P1Y5M13D' represents reported fact of one year, five months, and thirteen days." } } }, "auth_ref": ["r467"] }, "us-gaap_EmployeeStockOptionMember": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "EmployeeStockOptionMember", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureCommonSharesScheduleOfSharesReservedForFutureIssuanceUnderThePlanDetails", "http://engene.com/20241031/taxonomy/role/DisclosureNetLossPerShareSummaryOfDilutedNetLossPerShareAttributableToCommonShareholdersDetails", "http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationAdditionalInformationDetails", "http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationScheduleOfAssumptionsUsedToDetermineGrantdateFairValueOfStockOptionsDetails", "http://xbrl.sec.gov/ecd/role/AwardTimingDisclosure"], "lang": { "en-us": { "role": { "label": "Employee Stock Option [Member]", "terseLabel": "Employee Stock Option", "verboseLabel": "Options to purchase common shares", "documentation": "Share-based payment arrangement granting right, subject to vesting and other restrictions, to purchase or sell certain number of shares at predetermined price for specified period of time." } } }, "auth_ref": [] }, "engn_EndOfTermCharge": { "xbrltype": "monetaryItemType", "nsuri": "http://engene.com/20241031", "localname": "EndOfTermCharge", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureNotesPayableAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "End of term charge", "label": "End of Term Charge", "documentation": "End of term charge." } } }, "auth_ref": [] }, "engn_EndOfTermFeePercentage": { "xbrltype": "percentItemType", "nsuri": "http://engene.com/20241031", "localname": "EndOfTermFeePercentage", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureNotesPayableAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "End of term fee percentage", "label": "End of Term Fee Percentage", "documentation": "End of term fee percentage." } } }, "auth_ref": [] }, "dei_EntityAddressAddressLine1": { "xbrltype": "normalizedStringItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "EntityAddressAddressLine1", "presentation": ["http://engene.com/20241031/taxonomy/role/DocumentDocumentAndEntityInformation"], "lang": { "en-us": { "role": { "label": "Entity Address, Address Line One", "documentation": "Address Line 1 such as Attn, Building Name, Street Name" } } }, "auth_ref": [] }, "dei_EntityAddressCityOrTown": { "xbrltype": "normalizedStringItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "EntityAddressCityOrTown", "presentation": ["http://engene.com/20241031/taxonomy/role/DocumentDocumentAndEntityInformation"], "lang": { "en-us": { "role": { "label": "Entity Address, City or Town", "documentation": "Name of the City or Town" } } }, "auth_ref": [] }, "dei_EntityAddressCountry": { "xbrltype": "countryCodeItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "EntityAddressCountry", "presentation": ["http://engene.com/20241031/taxonomy/role/DocumentDocumentAndEntityInformation"], "lang": { "en-us": { "role": { "label": "Entity Address, Country", "documentation": "ISO 3166-1 alpha-2 country code." } } }, "auth_ref": [] }, "dei_EntityAddressPostalZipCode": { "xbrltype": "normalizedStringItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "EntityAddressPostalZipCode", "presentation": ["http://engene.com/20241031/taxonomy/role/DocumentDocumentAndEntityInformation"], "lang": { "en-us": { "role": { "label": "Entity Address, Postal Zip Code", "documentation": "Code for the postal or zip code" } } }, "auth_ref": [] }, "dei_EntityAddressStateOrProvince": { "xbrltype": "stateOrProvinceItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "EntityAddressStateOrProvince", "presentation": ["http://engene.com/20241031/taxonomy/role/DocumentDocumentAndEntityInformation"], "lang": { "en-us": { "role": { "label": "Entity Address, State or Province", "documentation": "Name of the state or province." } } }, "auth_ref": [] }, "dei_EntityCentralIndexKey": { "xbrltype": "centralIndexKeyItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "EntityCentralIndexKey", "presentation": ["http://engene.com/20241031/taxonomy/role/DocumentDocumentAndEntityInformation"], "lang": { "en-us": { "role": { "terseLabel": "CIK", "label": "Entity Central Index Key", "documentation": "A unique 10-digit SEC-issued value to identify entities that have filed disclosures with the SEC. It is commonly abbreviated as CIK." } } }, "auth_ref": ["r961"] }, "dei_EntityCommonStockSharesOutstanding": { "xbrltype": "sharesItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "EntityCommonStockSharesOutstanding", "presentation": ["http://engene.com/20241031/taxonomy/role/DocumentDocumentAndEntityInformation"], "lang": { "en-us": { "role": { "label": "Entity Common Stock, Shares Outstanding", "documentation": "Indicate number of shares or other units outstanding of each of registrant's classes of capital or common stock or other ownership interests, if and as stated on cover of related periodic report. Where multiple classes or units exist define each class/interest by adding class of stock items such as Common Class A [Member], Common Class B [Member] or Partnership Interest [Member] onto the Instrument [Domain] of the Entity Listings, Instrument." } } }, "auth_ref": [] }, "dei_EntityCurrentReportingStatus": { "xbrltype": "yesNoItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "EntityCurrentReportingStatus", "presentation": ["http://engene.com/20241031/taxonomy/role/DocumentDocumentAndEntityInformation"], "lang": { "en-us": { "role": { "label": "Entity Current Reporting Status", "documentation": "Indicate 'Yes' or 'No' whether registrants (1) have filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that registrants were required to file such reports), and (2) have been subject to such filing requirements for the past 90 days. This information should be based on the registrant's current or most recent filing containing the related disclosure." } } }, "auth_ref": [] }, "dei_EntityDomain": { "xbrltype": "domainItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "EntityDomain", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureDescriptionOfBusinessAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "All Entities", "label": "Entity [Domain]", "documentation": "All the names of the entities being reported upon in a document. Any legal structure used to conduct activities or to hold assets. Some examples of such structures are corporations, partnerships, limited liability companies, grantor trusts, and other trusts. 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about the financial instruments, assets, and liabilities would include: (1) the fair value of the required items together with their carrying amounts (as appropriate); (2) for
items for which it is not practicable to estimate fair value, disclosure would include: (a) information pertinent to estimating fair value (including, carrying amount, effective
interest rate, and maturity, and (b) the reasons why it is not practicable to estimate fair value; (3) significant concentrations of credit risk including: (a) information about the
activity, region, or economic characteristics identifying a concentration, (b) the maximum amount of loss the entity is exposed to based on the gross fair value of the related
item, (c) policy for requiring collateral or other security and information as to accessing such collateral or security, and (d) the nature and brief description of such collateral
or security; (4) quantitative information about market risks and how such risks are managed; (5) for items measured on both a recurring and nonrecurring basis information
regarding the inputs used to develop the fair value measurement; and (6) for items presented in the financial statement for which fair value measurement is elected: (a)
information necessary to understand the reasons for the election, (b) discussion of the effect of fair value changes on earnings, (c) a description of [similar groups] items for
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Includes, but is not limited to, interest and penalties, reconciliation of unrecognized tax benefits, unrecognized tax benefits that would affect the effective tax rate, tax years that remain subject to examination by tax jurisdictions, and information about positions for which it is reasonably possible that amounts unrecognized will significantly change within 12 months." } } }, "auth_ref": ["r1171"] }, "us-gaap_IncomeTaxDisclosureAbstract": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "IncomeTaxDisclosureAbstract", "lang": { "en-us": { "role": { "label": "Income Tax Disclosure [Abstract]" } } }, "auth_ref": [] }, "us-gaap_IncomeTaxDisclosureTextBlock": { "xbrltype": "textBlockItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "IncomeTaxDisclosureTextBlock", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxes"], "lang": { "en-us": { "role": { "terseLabel": "Income Taxes", "label": "Income Tax Disclosure [Text Block]", "documentation": "The entire disclosure for income tax." } } }, "auth_ref": ["r209", "r478", "r483", "r492", "r493", "r494", "r496", "r502", "r513", "r515", "r516", "r517", "r768", "r920"] }, "us-gaap_IncomeTaxExpenseBenefit": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "IncomeTaxExpenseBenefit", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesSummaryOfComponentsOfTheProvisionForRecoveryOfIncomeTaxesDetails", "http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementsOfOperationsAndComprehensiveLoss"], "lang": { "en-us": { "role": { "totalLabel": "Total income tax expense (benefit)", "label": "Income Tax Expense (Benefit)", "terseLabel": "Provision for (recovery of) income taxes", "documentation": "Amount of current income tax expense (benefit) and deferred income tax expense (benefit) pertaining to continuing operations." } } }, "auth_ref": ["r148", 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Includes, but is not limited to, payment to settle zero-coupon bond for accreted interest of debt discount and debt instrument with insignificant coupon interest rate in relation to effective interest rate of borrowing attributable to accreted interest of debt discount." } } }, "auth_ref": ["r197", "r200", "r201"] }, "engn_InvestissementQuebecMember": { "xbrltype": "domainItemType", "nsuri": "http://engene.com/20241031", "localname": "InvestissementQuebecMember", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureRelatedPartyTransactionsAdditionalInformationDetails"], "lang": {

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Includes, but is not limited to, interest expense for finance lease, amortization of right-of-use asset for finance lease, operating lease cost, short-term lease cost, variable lease cost and sublease income." } } }, "auth_ref": ["r1204"] }, "us-gaap_LeaseExpirationDate1": { "xbrltype": "dateItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LeaseExpirationDate1", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Lease expiration date", "label": "Lease Expiration Date", "documentation": "Date which lease or group of leases is set to expire, in YYYY-MM-DD format." } } }, "auth_ref": [] }, "engn_LeaseExpirationMonthAndYear": { "xbrltype": "gYearMonthItemType", "nsuri": "http://engene.com/20241031", "localname": "LeaseExpirationMonthAndYear", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Lease expiration month and year", "label": "Lease Expiration Month and Year", "documentation": "Lease expiration month and year." } } }, "auth_ref": [] }, "us-gaap_LeaseholdImprovementsMember": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LeaseholdImprovementsMember", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosurePropertyAndEquipmentNetSummaryOfPropertyAndEquipmentDetails", "http://engene.com/20241031/taxonomy/role/DisclosureSummaryOfSignificantAccountingPoliciesSummaryOfEstimatedUsefulLifeOfEachAssetDetails"], "lang": { "en-us": { "role": { "terseLabel": "Leasehold Improvements", "label": "Leasehold Improvements [Member]", "documentation": "Additions or improvements to assets held under a lease arrangement." } } }, "auth_ref": ["r114", "r627"] }, "us-gaap_LeasesAbstract": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LeasesAbstract", "lang": { "en-us": { "role": { "label": "Leases [Abstract]" } } }, "auth_ref": [] }, "dei_LegalEntityAxis": { "xbrltype": "stringItemType", "nsuri": "http://xbrl.sec.gov/dei/2024", "localname": "LegalEntityAxis", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureDescriptionOfBusinessAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Legal Entity:", "label": "Legal Entity [Axis]", "documentation": "The set of legal entities associated with a report." } } }, "auth_ref": [] }, "us-gaap_LesseeDisclosureAbstract": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeDisclosureAbstract", "lang": { "en-us": { "role": { "label": "Lessee Disclosure [Abstract]" } } }, "auth_ref": [] }, "us-gaap_LesseeLeaseDescriptionLineItems": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeLeaseDescriptionLineItems", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Lessee, Lease, Description [Line Items]", "documentation": "Line items represent financial concepts included in a table. These concepts are used to disclose reportable information associated with domain members defined in one or many axes to the table." } } }, "auth_ref": ["r618", "r628"] }, "us-gaap_LesseeLeaseDescriptionTable": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeLeaseDescriptionTable", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Lessee, Lease, Description [Table]", "documentation": "Disclosure of information about lessee's leases." } } }, "auth_ref": ["r618", "r628"] }, "us-gaap_LesseeLeasesPolicyTextBlock": { "xbrltype": "textBlockItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeLeasesPolicyTextBlock", "presentation": ["http://engene.com/20241031/taxonomy/role/SummaryOfSignificantAccountingPoliciesPolicies"], "lang": { "en-us": { "role": { "terseLabel": "Leases", "label": "Lessee, Leases [Policy Text Block]", "documentation": "Disclosure of accounting policy for leasing arrangement entered into by lessee." } } }, "auth_ref": ["r617"] }, "us-gaap_LesseeOperatingLeaseExistenceOfOptionToExtend": { "xbrltype": "booleanItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeOperatingLeaseExistenceOfOptionToExtend", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Operating lease, option to extend", "label": "Lessee, Operating Lease, Existence of Option to Extend [true false]", "documentation": "Indicates (true false) whether lessee has option to extend operating lease." } } }, "auth_ref": ["r619"] }, "engn_LesseeOperatingLeaseExtendedTerm": { "xbrltype": "gYearMonthItemType", "nsuri": "http://engene.com/20241031", "localname": "LesseeOperatingLeaseExtendedTerm", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Operating lease extended term", "label": "Lessee, Operating Lease, Extended Term", "documentation": "Lessee, operating lease, extended term." } } }, "auth_ref": [] }, "us-gaap_LesseeOperatingLeaseLiabilityMaturityTableTextBlock": { "xbrltype": "textBlockItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeOperatingLeaseLiabilityMaturityTableTextBlock", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesTables"], "lang": { "en-us": { "role": { "label": "Lessee, Operating Lease, Liability, to be Paid, Maturity [Table Text Block]", "terseLabel": "Schedule of Maturities of Operating Lease Liabilities", "documentation": "Tabular disclosure of undiscounted cash flows of lessee's operating lease liability. Includes, but is not limited to, reconciliation of undiscounted cash flows to operating lease liability recognized in statement of financial position." } } }, "auth_ref": ["r1205"] }, "us-gaap_LesseeOperatingLeaseLiabilityPaymentsDue": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeOperatingLeaseLiabilityPaymentsDue", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesAdditionalInformationDetails", "http://engene.com/20241031/taxonomy/role/DisclosureLeasesScheduleOfMaturitiesOfOperatingLeaseLiabilitiesDetails"], "lang": { "en-us": { "role": { "terseLabel": "Additional lease commitments to be paid", "label": "Lessee, Operating Lease, Liability, to be Paid", "totalLabel": "Total", "documentation": "Amount of lessee's undiscounted obligation for lease payment for operating lease." } } }, "auth_ref": ["r626"] }, "us-gaap_LesseeOperatingLeaseLiabilityPaymentsDueAfterYearFive": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeOperatingLeaseLiabilityPaymentsDueAfterYearFive", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesScheduleOfMaturitiesOfOperatingLeaseLiabilitiesDetails"], "lang": { "en-us": { "role": { "label": "Lessee, Operating Lease, Liability, to be Paid, after Year Five", "terseLabel": "Thereafter", "documentation": "Amount of lessee's undiscounted obligation for lease payment for operating lease due after fifth fiscal year following current fiscal year. Excludes interim and annual periods when interim periods are reported from current statement of financial position date (rolling approach)." } } }, "auth_ref": ["r626"] }, "us-gaap_LesseeOperatingLeaseLiabilityPaymentsDueNextTwelveMonths": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeOperatingLeaseLiabilityPaymentsDueNextTwelveMonths", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesScheduleOfMaturitiesOfOperatingLeaseLiabilitiesDetails"], "lang": { "en-us": { "role": { "label": "Lessee, Operating Lease, Liability, to be Paid, Year One", "terseLabel": "2025", "documentation": "Amount of lessee's undiscounted obligation for lease payment for operating lease to be paid in next fiscal year following current fiscal year. Excludes interim and annual periods when interim periods are reported from current statement of financial position date (rolling approach)." } } }, "auth_ref": ["r626"] }, "us-gaap_LesseeOperatingLeaseLiabilityPaymentsDueYearFive": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "LesseeOperatingLeaseLiabilityPaymentsDueYearFive", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureLeasesScheduleOfMaturitiesOfOperatingLeaseLiabilitiesDetails"], "lang": { "en-us": { "role": { "label": "Lessee, Operating Lease, Liability, to be Paid, Year Five", "terseLabel": "2029", "documentation": "Amount of lessee's undiscounted obligation for lease payment for operating lease to be paid in fifth fiscal year following current fiscal year. Excludes interim and annual periods when interim periods are reported from current statement of financial position date (rolling approach)." } } }, "auth_ref": ["r626"] }, "us-gaap_LesseeOperatingLeaseLiabilityPaymentsDueYearFour": { "xbrltype": "monetaryItemType", "nsuri":

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These are debt arrangements that originally required repayment more than twelve months after issuance or greater than the normal operating cycle of the company, if longer." } } }, "auth_ref": ["r20", "r41", "r1127", "r1128", "r1129"] }, "us-gaap_MarketableSecuritiesCurrent": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "MarketableSecuritiesCurrent", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedBalanceSheets1"], "lang": { "en-us": { "role": { "label": "Marketable Securities, Current", "terseLabel": "Marketable securities - short term", "documentation": "Amount of investment in marketable security, classified as current." } } }, "auth_ref": ["r1087"] }, "us-gaap_MarketableSecuritiesLineItems": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "MarketableSecuritiesLineItems", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureMarketableSecuritiesAdditionalInformationDetails", "http://engene.com/20241031/taxonomy/role/DisclosureMarketableSecuritiesScheduleOfMarketableSecuritiesDetails"], "lang": { "en-us": { "role": { "label": "Marketable Securities [Line Items]", "documentation": "Line items represent financial concepts included in a table. 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research and development assets acquired in transaction other than business combination or joint venture formation or both. Excludes write-down of intangible asset acquired
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contributed capital or to reduce goodwill or other noncurrent intangible assets of an acquired entity, adjustments of a deferred tax liability or asset for enacted changes in tax
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These concepts are used to disclose reportable information associated with domain members defined in one or many axes to the table." } } }, "auth_ref": ["r431", "r432", "r434", "r435", "r436", "r438", "r439", "r440", "r441", "r442", "r443", "r444", "r445", "r446", "r447", "r448", "r449", "r450", "r451", "r452", "r453", "r454", "r455", "r458", "r459", "r460", "r461", "r462"] }, "us-gaap_ShareBasedCompensationArrangementByShareBasedPaymentAwardNumberOfSharesAuthorized": { "xbrltype": "sharesItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "ShareBasedCompensationArrangementByShareBasedPaymentAwardNumberOfSharesAuthorized", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Share-Based Compensation Arrangement by Share-Based Payment Award, Number of Shares Authorized", "terseLabel": "Number of shares authorized increased", "documentation":

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exercise of options or other equity-based awards under the plan; and 2) shares (or other type of equity) reserved for issuance on granting of outstanding awards, net of cancellations and forfeitures, if applicable." } } }, "auth_ref": ["r57"] }, "engn_ShareBasedCompensationArrangementByShareBasedPaymentAwardOptionToPurchaseCommonShares": { "xbrltype": "sharesItemType", "nsuri": "http://engene.com/20241031", "localname": "ShareBasedCompensationArrangementByShareBasedPaymentAwardOptionToPurchaseCommonShares", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Options to purchase common shares", "label": "Share Based Compensation Arrangement By Share Based Payment Award Option to Purchase Common Shares", "documentation": "Share based compensation arrangement by share based payment award option to purchase common shares." } } }, "auth_ref": [] }, 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Includes, but is not limited to, unvested options for which requisite service period has not been rendered but that are expected to vest based on achievement of performance condition, if forfeitures are recognized when they occur." } } }, "auth_ref": ["r455"] }, "us-gaap_ShareBasedCompensationArrangementByShareBasedPaymentAwardOptionsVestedAndExpectedToVestOutstandingAggregateIntrinsicValue": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "ShareBasedCompensationArrangementByShareBasedPaymentAwardOptionsVestedAndExpectedToVestOutstandingAggregateIntrinsicValue", "crdr": "debit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationSummaryOfStockOptionActivityDetails"], "lang": { "en-us": { "role": { "terseLabel": "Aggregate Intrinsic Value, Options vested and exercisable", "label": "Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and Expected to Vest, Outstanding, Aggregate Intrinsic Value", "documentation": "Amount by which current fair value of underlying stock exceeds exercise price of fully vested and expected to vest options outstanding. Includes, but is not limited to, unvested options for which requisite service period has not been rendered but that are expected to vest based on achievement of performance condition, if forfeitures are recognized when they occur." } } }, "auth_ref": ["r454"] }, "us-gaap_ShareBasedCompensationArrangementByShareBasedPaymentAwardOptionsVestedAndExpectedToVestOutstandingNumber": { "xbrltype": "sharesItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "ShareBasedCompensationArrangementByShareBasedPaymentAwardOptionsVestedAndExpectedToVestOutstandingNumber", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureCommonSharesScheduleOfSharesReservedForFutureIssuanceUnderThePlanParentheticalDetails", "http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "verboseLabel": "Remaining options vesting", "terseLabel": "Shares Vesting", "label": "Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested and Expected to Vest, Outstanding, Number", "documentation": "Number of fully vested and expected to vest options outstanding that can be converted into shares under option plan. 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gaap/2024", "localname": "ShareBasedCompensationArrangementsByShareBasedPaymentAwardAwardTypeAndPlanNameDomain", "presentation": [
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"http://engene.com/20241031/taxonomy/role/DisclosureSharebasedCompensationScheduleOfAssumptionsUsedToDetermineGrantdateFairValueOfStockOptionsDetails",
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Includes, but is not limited to, significant settlements of income tax disputes, and unusual tax positions or infrequent actions taken by the entity, including tax assessment reversal, and IRS tax settlement." } } }, "auth_ref": ["r1176"] }, "us-gaap_TaxPeriodAxis": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "TaxPeriodAxis", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Tax Period [Axis]", "documentation": "Information by period subject to enacted tax law." } } }, "auth_ref": ["r1172"] }, "us-gaap_TaxPeriodDomain": { "xbrltype": "domainItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "TaxPeriodDomain", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureIncomeTaxesAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Tax Period [Domain]", "documentation": "Identified tax period." } } }, "auth_ref": ["r1172"] }, "us-gaap_TemporaryEquityCarryingAmountAttributableToParent": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "TemporaryEquityCarryingAmountAttributableToParent", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementsOfRedeemableConvertiblePreferredSharesAndShareholdersEquityDeficit1"], "lang": { "en-us": { "role": { "terseLabel": "Redeemable convertible preferred shares value", "label": "Temporary Equity, Carrying Amount, Attributable to Parent", "periodEndLabel": "Ending balance", "periodStartLabel": "Beginning balance", "documentation": "Carrying amount, attributable to parent, of an entity's issued and outstanding stock which is not included within permanent equity. Temporary equity is a security with redemption features that are outside the control of the issuer, is not classified as an asset or liability in conformity with GAAP, and is not mandatorily redeemable. Includes any type of security that is redeemable at a fixed or determinable price or on a fixed or determinable date or dates, is redeemable at the option of the holder, or has conditions for redemption which are not solely within the control of the issuer. Includes stock with a put option held by an ESOP and stock redeemable by a holder only in the event of a change in control of the issuer." } } }, "auth_ref": ["r360", "r362", "r363", "r364", "r367", "r368", "r473", "r727"] }, "us-gaap_TemporaryEquityRedemptionPricePerShare": { "xbrltype": "perShareItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "TemporaryEquityRedemptionPricePerShare", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureDescriptionOfBusinessAdditionalInformationDetails"], "lang": { "en-us": { "role": { "label": "Temporary Equity, Redemption Price Per Share", "terseLabel": "Temporary equity redemption price per share", "documentation": "Amount to be paid per share that is classified as temporary equity by entity upon redemption. Temporary equity is a security with redemption features that are outside the control of the issuer, is not classified as an asset or liability in conformity with GAAP, and is not mandatorily redeemable. Includes any type of security that is redeemable at a fixed or determinable price or on a fixed or determinable date or dates, is redeemable at the option of the holder, or has conditions for redemption which are not solely within the control of the issuer. If convertible, the issuer does not control the actions or events necessary to issue the maximum number of shares that could be required to be delivered under the conversion option if the holder exercises the option to convert the stock to another class of equity. If the security is a warrant or a rights issue, the warrant or rights issue is considered to be temporary equity if the issuer cannot demonstrate that it would be able to deliver upon the exercise of the option by the holder in all cases. Includes stock with put option held by ESOP and stock redeemable by holder only in the event of a change in control of the issuer." } } }, "auth_ref": ["r21", "r45"] }, "us-gaap_TemporaryEquitySharesOutstanding": { "xbrltype": "sharesItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "TemporaryEquitySharesOutstanding", "presentation": ["http://engene.com/20241031/taxonomy/role/StatementConsolidatedStatementsOfRedeemableConvertiblePreferredSharesAndShareholdersEquityDeficit1"], "lang": { "en-us": { "role": { "label": "Temporary Equity, Shares Outstanding", "periodEndLabel": "Ending balance (in shares)", "periodStartLabel": "Beginning balance (in shares)", "terseLabel": "Temporary equity shares outstanding", "documentation": "The number of securities classified as temporary equity that have been issued and are held by the entity's shareholders. Securities outstanding equals securities issued minus securities held in treasury. Temporary equity is a security with redemption features that are outside the control of the issuer, is not classified as an asset or liability in conformity with GAAP, and is not mandatorily redeemable. Includes any type of security that is redeemable at a fixed or determinable price or on a fixed or determinable date or dates, is redeemable at the option of the holder, or has conditions for redemption which are not solely within the control of the issuer. If convertible, the issuer does not control the actions or events necessary to issue the maximum number of shares that could be required to be delivered under the conversion option if the holder exercises the option to convert the stock to another class of equity. If the security is a warrant or a rights issue, the warrant or rights issue is considered to be temporary equity if the issuer cannot demonstrate that it would be able to deliver upon the exercise of the option by the holder in all cases. 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US Government Corporations and Agencies. Investments in such US Government Corporations may include debt securities issued by the Government National Mortgage
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Department of the Treasury, US Government Agencies and US Government-sponsored Enterprises. Such securities may include treasury bills (short-term maturities - one year
or less), treasury notes (intermediate term maturities - two to ten years), and treasury bonds (long-term maturities - ten to thirty years), debt securities issued by the
Government National Mortgage Association (Ginnie Mae) and debt securities issued by the Federal National Mortgage Association (Fannie Mae) or the Federal Home Loan
Mortgage Corporation (Freddie Mac)." } } }, "auth_ref": ["r718", "r911", "r937", "r948", "r1250"] }, "us-gaap_USTreasurySecuritiesMember": { "xbrltype": "domainItemType",
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securities issued by the United States Department of the Treasury and backed by the United States government. Such securities primarily consist of treasury bills (short-term maturities - one year or less), treasury notes (intermediate term maturities - two to ten years), and treasury bonds (long-term maturities - ten to thirty years)." } } }, "auth_ref": ["r892", "r911", "r913", "r923", "r1218"] }, "ecd_UndrlygSecurityMktPriceChngPct": { "xbrltype": "pureItemType", "nsuri": "http://xbrl.sec.gov/ecd/2024", "localname": "UndrlygSecurityMktPriceChngPct", "presentation": ["http://xbrl.sec.gov/ecd/role/AwardTimingDisclosure"], "lang": { "en-us": { "role": { "label": "Underlying Security Market Price Change, Percent", "terseLabel": "Underlying Security Market Price Change" } } }, "auth_ref": ["r1048"] }, "us-gaap_UnrecognizedTaxBenefitsIncomeTaxPenaltiesAccrued": { "xbrltype": "monetaryItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "UnrecognizedTaxBenefitsIncomeTaxPenaltiesAccrued", "crdr": "credit", "presentation": 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five months, and thirteen days." } } }, "auth_ref": ["r1183", "r1184", "r1185"] }, "engn_WarrantsIssuedDuringPeriodValue": { "xbrltype": "monetaryItemType", "nsuri": "http://engene.com/20241031", "localname": "WarrantsIssuedDuringPeriodValue", "crdr": "credit", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureReverseRecapitalizationAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Warrants issued during period, value", "label": "Warrants Issued During Period, Value", "documentation": "Warrants issued during period, value." } } }, "auth_ref": [] }, "engn_WarrantsToPurchaseRedeemableConvertiblePreferredSharesMember": { "xbrltype": "domainItemType", "nsuri": "http://engene.com/20241031", "localname": "WarrantsToPurchaseRedeemableConvertiblePreferredSharesMember", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureCommonSharesScheduleOfSharesReservedForFutureIssuanceUnderThePlanDetails", "http://engene.com/20241031/taxonomy/role/DisclosureNetLossPerShareSummaryOfDilutedNetLossPerShareAttributableToCommonShareholdersDetails"], "lang": { "en-us": { "role": { "verboseLabel": "Warrants to Purchase Redeemable Convertible Preferred Shares", "terseLabel": "Warrants to purchase redeemable convertible preferred shares", "label": "Warrants to Purchase Redeemable Convertible Preferred Shares [Member]", "documentation": "Warrants to purchase redeemable convertible preferred shares." } } }, "auth_ref": [] }, "engn_WarrantsToPurchaseSharesOfCommonStock": { "xbrltype": "sharesItemType", "nsuri": "http://engene.com/20241031", "localname": "WarrantsToPurchaseSharesOfCommonStock", "presentation": ["http://engene.com/20241031/taxonomy/role/DisclosureConvertibleDebenturesAdditionalInformationDetails", "http://engene.com/20241031/taxonomy/role/DisclosureRelatedPartyTransactionsAdditionalInformationDetails"], "lang": { "en-us": { "role": { "terseLabel": "Warrants to purchase shares of 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issued and outstanding that are used in calculating diluted EPS or earnings per unit (EPU), determined based on the timing of issuance of shares or units in the period." } } }, "auth_ref": ["r235", "r246"] }, "us-gaap_WeightedAverageNumberOfSharesOutstandingAbstract": { "xbrltype": "stringItemType", "nsuri": "http://fasb.org/us-gaap/2024", "localname": "WeightedAverageNumberOfSharesOutstandingAbstract", "presentation": [

~~***style="color:#000000;white-space:pre-wrap;font-weight:bold;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">Cybersecurity Risk Management and Strategy </p><p style="text-indent:6.667%;font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:12pt;text-align:justify;">We have implemented cybersecurity risk management procedures, in accordance with our risk profile and business size, that are designed to identify, assess, and mitigate risks from current and emerging cybersecurity threats. Our cybersecurity procedures, which are informed by the National Institute of Standards and Technology cybersecurity framework, are supported by a third-party managed services provider that assists us in managing our IT systems. We maintain cyber insurance coverage; however, such insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks, and other related breaches. </p><p style="text-indent:6.667%;font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:12pt;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-***~~

~~content;">Our cybersecurity procedures are comprised of a variety of tools designed to protect our data and information technology systems, including but not limited to endpoint protection and network security measures, that are supported by our third-party service providers. We also have a process to require our employees to undergo cybersecurity awareness training. Further, we plan to implement a process to review risks to our Company in connection with certain third-party providers and vendors, which we expect will involve assessments through vendor questionnaires, as appropriate.</p><p style="text-indent:6.667%;font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:12pt;text-align:justify;">To date, we have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party IT service providers and vendors have from time to time experienced threats that could affect our information or systems. For more information, see, “Risk Factors,” in this Annual Report.</p><p style="font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:12pt;text-align:justify;">Cybersecurity Governance</p><div><p style="text-indent:6.667%;font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:12pt;text-align:justify;"><span~~

~~style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">Our cybersecurity program is managed and directed by our Vice President, Information Technology, or IT, who has approximately 20 years of experience in information technology and information systems management. Our Vice President, IT reports to our Chief Financial Officer. </p><p style="text-indent:6.667%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight.<span~~

~~style="font-size:10pt;font-family:Times New Roman;"> Our Audit Committee is responsible for overseeing the Company’s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes cybersecurity risk. A cybersecurity update is provided at least annually, or more frequently as needed, to the Audit Committee by members of management responsible for managing cybersecurity risks.</p></div>truetruefalse<p style="text-indent:6.667%;font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:12pt;text-align:justify;">Our cybersecurity program is managed and directed by our Vice President, Information Technology, or IT, who has approximately 20 years of experience in~~

~~***information technology and information systems management. Our Vice President, IT reports to our Chief Financial Officer. </p><p style="text-indent:6.667%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">One of the key functions of our Board of Directors is informed oversight of our risk management process. Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight. <span style="font-***~~

~~size:10pt;font-family:Times New Roman;">Our Audit Committee is responsible for overseeing the Company’s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes cybersecurity risk. A cybersecurity update is provided at least annually, or more frequently as needed, to the Audit Committee by members of management responsible for managing cybersecurity risks.</p>Our cybersecurity program is managed and directed by our Vice President, Information Technology, or IT, who has approximately 20 years of experience in information technology and information systems management.One of the key functions of our Board of Directors is informed oversight of our risk management process.<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-~~

~~***content;"> Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight.One of the key functions of our Board of Directors is informed oversight of our risk management process.Our Board of Directors does not have a standing risk management committee, and administers this oversight function both directly as a whole, and through various standing committees that address risks inherent in their respective areas of oversight. Our Audit Committee is responsible for overseeing the Company’s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes***~~

~~cybersecurity risk. truetrueOur Audit Committee is responsible for overseeing the Company’s enterprise risk management processes as well as our policies with respect to risk assessment and risk management, which includes cybersecurity risk.A cybersecurity update is provided at least annually, or more frequently as needed, to the Audit Committee by members of management responsible for managing cybersecurity risks. falsefalsefalsefalse<p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:5pt;text-align:left;">Opinion on the Consolidated Financial Statements</p><p style="font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:10pt;text-align:left;">We have audited the accompanying consolidated balance sheets of enGene Holdings Inc. (the “Company”) as of October 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred shares and shareholders’ equity (deficit), and cash flows for the years then ended, and the related notes (collectively, the “consolidated financial statements”). In our opinion, the~~

~~***consolidated financial statements present fairly, in all***~~
~~***material respects, the financial position of the Company***~~
~~***as of October 31, 2024 and 2023, and the results of its***~~
~~***operations and its cash flows for the years then ended, in***~~
~~***conformity with U.S. generally accepted accounting***~~
~~***principles.***~~
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~~Roman;min-width:fit-content;">1. Description of Business</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">enGene Holdings Inc. (together with its consolidated subsidiaries “enGene” or the “Company”) formed in connection with the Merger Agreement (as defined below) was incorporated as 14963148 Canada Inc. under the federal laws of Canada on April 24, 2023 and changed its name to enGene Holdings Inc. on May 9, 2023. On October 31, 2023, enGene Holdings Inc. continued from being a corporation incorporated under and governed by the Canada Business Corporations Act to a company continued to and governed by the Business Corporations Act (British Columbia). </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company is a clinical-stage biotechnology company focused on developing genetic medicines to improve the lives of patients, and its head office is located in Montreal, Quebec, Canada. The Company is developing non-viral genetic medicines based on its novel and proprietary dually derived chitosan, or “DDX”, gene delivery platform, which allows localized delivery of multiple gene cargos directly to mucosal tissues and other organs.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-~~

~~***weight:bold;font-size:10pt;font-family:Times New Roman;font-style:italic;min-width:fit-content;">Merger with Forbion European Acquisition Corp.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Forbion European Acquisition Corporation (“FEAC”) was a special purpose acquisition company (“SPAC”), incorporated as a Cayman Island exempted company on August 9, 2021 and formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more business or entities. On October 31, 2023 (the “Closing Date”), the Company, FEAC, and enGene Inc., consummated the merger (the “Reverse Recapitalization”) pursuant to a business combination agreement, dated as of May 16, 2023 (the “Merger Agreement”). </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The transaction was accounted for as a “reverse recapitalization” in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). Under this method of accounting, FEAC was treated as the “acquired” company for financial reporting purposes. This determination is primarily based on the fact that subsequent to the Reverse Recapitalization, senior management of Old enGene continued as senior management of the combined company; Old enGene identified a majority of the members of the board of directors of the combined company; the name of the combined company is enGene***~~

~~Holdings Inc. and it utilized Old enGene’s current headquarters, and Old enGene’s operations comprise the ongoing operations of the combined company. Accordingly, for accounting purposes, the Company is considered to be a continuation of Old enGene, with the net identifiable assets of FEAC deemed to have been acquired by Old enGene in exchange for Old enGene common shares accompanied by a recapitalization, with no goodwill or intangible assets recorded. The number of redeemable convertible preferred shares, number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization, have been retrospectively restated to reflect an exchange ratio of approximately 0.18048 (the “Exchange Ratio”) established in the Merger Agreement. Operations prior to the Reverse Recapitalization are those of Old enGene.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">As a result of the Reverse Recapitalization, the Company became a publicly traded company, and listed its Common Shares and warrants on the Nasdaq Global Market under the symbols “ENGN” and “ENGNW,” respectively, commencing trading on November 1, 2023,~~

~~with Old enGene, a subsidiary of the Company, continuing the existing business operations.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Liquidity and Going Concern </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In accordance with Accounting Standards Codification (“ASC”) 205-40, Going Concern, the Company has evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date these consolidated financial statements are issued.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company’s consolidated financial statements have been prepared assuming the Company will continue as a going concern, which presumes the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in~~

~~***the ordinary course of business.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">As an emerging growth entity, the Company has devoted substantially all of its resources since inception to organizing and staffing the Company, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, research and development activities for developing non-viral genetic medicines and other compounds, establishing arrangements with third parties for the manufacture of its product candidates and component materials, and providing general and administrative support for these operations. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future. The Company has not yet commercialized any product candidates and does not expect to generate revenue from sales of any product candidates or from other sources for several </p><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">years, if at all. The Company will need substantial additional funding to support its continuing operations and pursue its development strategy.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-***~~

~~***content;">The Company has incurred a net loss of $55.1 million and negative cash flows from operating activities of $48.3 million for year ended October 31, 2024, and, as of that date, has an accumulated deficit of $254.7 million. To date, the Company has not generated any revenues and has financed its liquidity needs primarily through the 2024 PIPE Financings, the Reverse Recapitalization and the PIPE financing conducted by the Company as part of the Reverse Recapitalization (the “PIPE Financing”), debt and convertible debentures, and issuance of redeemable convertible preferred shares and warrants.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company’s ability to continue as a going concern depends on its ability to successfully develop and commercialize its products, achieve and maintain profitable operations, as well as the adherence to***~~

~~conditions of outstanding loans. As of the issuance date of these consolidated financial statements, the Company expects that its existing cash and cash equivalents as of October 31, 2024 will be sufficient to fund its operating expenses and debt obligations requirements for at least the next 12 months from the issuance date of these consolidated financial statements. Effective from the Company’s first quarter interim condensed consolidated financial statements, the Company has ceased its disclosure of the existence of a material uncertainty that raised substantial doubt about the Company’s ability to continue as a going concern due to the February 2024 PIPE Financing.</p>000.0018048-55100000-48300000-254700000<p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">2. Summary of Significant Accounting Policies</p><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Basis of Presentation</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The accompanying consolidated financial statements are prepared in accordance with U.S. GAAP and include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been~~

~~eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and as amended by Accounting Standards Updates (“ASU’s”) of the Financial Accounting Standards Board (“FASB”).</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:6pt;text-align:justify;">The consolidated financial statements are expressed in US dollars. The consolidated financial statements have been prepared on a historical cost basis, except for items that are required to be accounted for at fair value.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">As the merger with FEAC has been accounted for as a reverse recapitalization, the historical operations of the Company represent that of Old enGene which is the accounting predecessor. The number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization have been retrospectively restated to reflect the Exchange Ratio of approximately 0.18048 established in the Merger Agreement. Please see Note 3, Reverse Recapitalization for additional information.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-~~

~~size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Use of Estimates</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The preparation of the Company’s consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include but are not limited to the accrual of research and development expenses, share-based payments and the recoverability of investment tax credits receivable and, in addition, for fiscal 2023: the valuations of common shares, redeemable convertible preferred shares, warrants to purchase redeemable convertible preferred shares, convertible debentures, and embedded derivatives on convertible debt. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Actual results could differ from those estimates and such differences may be material to the consolidated financial statements.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Segment~~

~~Information</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:6pt;text-align:justify;">Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates as a single business segment focused on research, discovery, and clinical development of human genetic medicine products. The majority of the Company’s tangible assets are held in Canada.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Risk of Concentrations of Credit and Off-Balance Sheet Risk</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits. Management believes that the Company is not currently exposed to significant credit risk as the Company’s deposits were held in custody at third-party financial institutions.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-~~

~~***space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">The Company's investment policy limits investments to certain types of securities issued by the U.S. Government and its agencies, as well as institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of marketable securities to the extent recorded on the Consolidated Balance Sheets. As of October 31, 2024 and 2023, the Company had no off-balance sheet concentrations of credit risk.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company is dependent on third-party CDMOs and CRO with whom it does business. In particular, the Company relies and expects to continue to***~~

~~***rely on a small number of manufacturers to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities in its programs. The Company also relies on a limited number of third-party CROs to perform research and development activities on its behalf. These programs could be adversely affected by significant interruption from these providers.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Cash and Cash Equivalents</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company considers all short-term, highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company’s cash and cash equivalents include bank balances, demand deposits and other short-term, highly liquid investments. The fair value of cash and cash equivalents approximate the amortized cost. The Company had $173.0 million of cash and cash equivalents as of October 31, 2024 and $81.5<span***~~

~~***style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;"> million of cash as of October 31, 2023 .</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Marketable securities</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company's marketable securities are maintained by investment managers and consist of money market funds, U.S. government agency securities and treasuries. If the remaining contractual maturity is within one year from the balance sheet date, the marketable securities are classified as current and otherwise, they are classified as non-current assets.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Investment in marketable securities is classified as available-for-sale and is reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale securities are reported as a separate component of stockholders' equity in other comprehensive loss. Premium or discounts from par value are amortized to investment income over the life of the underlying investment.</p><p style="text-***~~

~~indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company periodically evaluates the need for an allowance for credit losses. The evaluation includes consideration of several qualitative and quantitative factors, including whether it has plans to sell the security, whether it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis, and if the entity has the ability and intent to hold the security to maturity, and the portion of any unrealized loss that is the result of a credit loss. Factors considered in making these evaluations include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, expected cash flows from securities, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and the Company's strategy and intentions for holding the marketable security.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">When the fair value is below the amortized cost of the asset, an estimate of expected credit losses is made. The Company records credit losses in the consolidated statements of operations and comprehensive loss as a credit loss expense within other income, net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale securities.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-~~

~~***space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">Accrued interest receivable related to the Company's available-for-sale securities is presented within prepaids and other current assets on the Company's consolidated balance sheets. The Company has elected the practical expedient available to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivable associated with its marketable securities.</p></div><div><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Property and Equipment</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Property and equipment are comprised mainly of research and development equipment, computer hardware and software, office furniture and equipment, and leasehold improvements. Property and equipment are stated at cost less accumulated depreciation and accumulated impairment losses, if applicable. Depreciation expense is recognized using the straight-line method over the estimated useful life of each***~~

~~align:justify;">Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheet and any resulting gains or losses are included in the consolidated statements of operations and comprehensive loss in the period of disposal.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company reviews long-lived assets, such as property and equipment, for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. If indicators of impairment are present, the assets are tested for recoverability by comparing the carrying amount of the assets to the related estimated future undiscounted cash flows that the assets are expected to generate. If the expected undiscounted cash flows are less than the carrying value of the assets, then the assets are considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows. To date, no such impairment losses have been recorded.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Leases</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-~~

~~***align:justify;">The Company adopted FASB ASC 842 with an effective date of November 1, 2019, using the modified retrospective transition approach which uses the effective date as the date of initial application. In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use (“ROU”) asset and a lease liability on the consolidated balance sheet for all leases with an initial lease term of greater than 12 months. The Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-***~~

~~space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">Lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Fair Value Measurements of Financial Instruments</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in~~

~~one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable: </p><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6.3pt;justify-content:flex-start;align-items:baseline;margin-bottom:6pt;min-width:4.537%;text-align:left;">o<div style="width:100%;display:inline;">Level 1—Quoted prices in active markets for identical assets or liabilities.</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6.5pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;margin-right:10.269%;min-width:4.537%;text-align:justify;">o<div style="width:100%;display:inline;">Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6.1pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;margin-right:12.13%;min-width:4.537%;text-align:justify;"><span style="color:#231f20;white-space:pre-wrap;font-~~

~~size:10pt;font-family:Times New Roman;min-width:4.7521786492374725%;word-break:keep-all;display:inline-flex;justify-content:flex-start;">o<div style="width:100%;display:inline;"> Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.</div> </div><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">At October 31, 2024, financial instruments measured at fair value on a recurring basis include marketable securities (see Note 5, Marketable Securities, and Note 4, Fair Value Measurements). The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term nature.</p></div>~~

~~<div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;margin-right:12.13%;text-align:justify;">Fair Value Option</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company elected the fair value option of accounting of ASC 825 for all convertible debentures issued in fiscal 2023 from their issuance date in order to not have to bifurcate any embedded derivatives in accordance with ASC 815. The notes for which the fair value option of accounting is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the notes accounted for at fair value, which include accrued interest, if any, are recorded as a component of other expense (income), net in the consolidated statement of operations and comprehensive loss. The Company has not elected to present interest expense separately from changes in fair value and therefore will not present interest expense associated with the notes. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income. During the year ended October 31, 2023, the Company did not record any changes in fair value related to instrument-specific credit risk. All costs associated with the issuance of the convertible debentures accounted for using the fair value option were expensed upon issuance.</p></div> <div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;margin-right:12.13%;text-align:justify;"><span~~

~~***style="color:#000000;white-space:pre-wrap;font-weight:bold;font-size:10pt;font-family:Times New Roman;font-style:italic;min-width:fit-content;">Debt Issuance Costs</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company capitalizes certain legal, accounting, and other third-party fees that are directly associated with the issuance of debt not accounted for using the fair value option as debt issuance costs. Debt issuance costs are recorded as a direct reduction of the carrying amount of the associated debt on the Company’s consolidated balance sheets and amortized as interest expense on the Company’s consolidated statements of operations and comprehensive loss using the effective interest method.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;margin-right:12.13%;text-align:justify;">Convertible Debenture Embedded Derivative Liabilities</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company’s convertible debentures contained certain features that meet the definition of embedded derivatives requiring bifurcation from the convertible debenture instrument, for which the fair value option was not elected, as a separate compound derivative. The convertible debenture embedded derivative liabilities are initially measured at fair value on issuance and is subject to remeasurement at each***~~

~~reporting period with changes in fair value recognized in the change in fair value of derivative liabilities, net in the consolidated statements of operations and comprehensive loss. </p></div><p style="font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:0;text-align:left;"> </p><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;margin-right:12.13%;text-align:justify;">Common Share and Preferred Share Warrants</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company accounts for its common share warrants and redeemable convertible preferred shares warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants that have been determined to be classified as liabilities are recorded on the consolidated balance sheets at their fair value on the date of issuance and remeasured to fair value at each reporting period, with the changes in fair value recognized in the change in fair value of warrant liabilities, net in the consolidated statements of operations and comprehensive loss. The Company adjusted the liability for changes in the fair value of these warrants until the earlier of the exercise of the warrants, the expiration of the warrants, or until such time as the warrants were no longer considered liability.</p>~~

~~</div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Convertible Debentures</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company’s 2022 Notes (as defined in Note 9, Notes Payable) are convertible debentures that consist of a debt instrument, a minimum interest obligation, and a share conversion feature. Certain of the convertible debentures issued by the Company also included warrants to purchase redeemable convertible preferred shares, which were classified as liabilities. The Company identified embedded derivatives related to certain share conversion and repayment features within the convertible notes that required bifurcation as a single compound derivative instrument. At inception, the Company utilized the residual method to determine the value of the debt instrument based on the difference between gross proceeds and the estimated fair value of the embedded derivative and any warrants that were issued. The debt instrument is accounted for using the amortized cost method. The discounts on debt resulting from any issuance costs, embedded derivatives and warrants are amortized over the life of the debt using the effective interest method. The issuance costs allocated to the embedded derivatives and warrants are expensed at inception.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-weight:bold;font-size:10pt;font-family:Times New~~

~~Roman;font-style:italic;min-width:fit-content;">Research and Development Expenses</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Research and development expenses are comprised primarily of costs incurred for our drug discovery efforts and development of our product candidates. These expenses include salaries, employee benefits, and share-based compensation expense for our research and development personnel, materials, supplies, depreciation on and maintenance of research equipment, the cost of services provided by outside CROs and consultants to conduct research and development activities including costs of clinical trials and manufacturing, and the allocable portions of facility costs, such as rent, utilities, and general support services. All costs associated with research and development are expensed as incurred. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Management estimates the Company’s accrued research and development expenses as of each balance sheet date in the Company’s financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span~~

~~***style="color:#000000;white-space:pre-wrap;font-weight:bold;font-size:10pt;font-family:Times New Roman;font-style:italic;min-width:fit-content;">Patent Costs</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">All patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent-related costs are classified as general and administrative expenses within the Company’s consolidated statements of operations. </p></div><div><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Share-Based Compensation</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company has an incentive equity plan (the “2023 Incentive Equity Plan” or the “2023 Plan”), whereby employees render services as consideration for equity instruments. The 2023 Plan was adopted on October 31, 2023 upon the completion of the Reverse Recapitalization and superseded Old enGene’s employee stock option plan (the “ESOP”) and equity incentive plan (the “EIP”) (collectively, the “Old Plans”). The Company measures all share-based awards granted to employees, officers, directors and non-employees based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the***~~

~~***respective award. The Company accounts for forfeitures of its share-based awards as they occur. The Company issues share-based awards with service-based vesting conditions and awards with both performance and service-based vesting conditions. For share-based awards with service-based vesting conditions, the Company records the expense using the straight-line method including when such awards have graded vesting. For share-based awards with both performance and service-based vesting conditions, the Company records the expense using an accelerated attribution method, once the performance conditions are considered probable of being achieved, using management’s best estimate.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the Company’s common shares, expected share price volatility, the expected term of the award, the risk-free interest rate for a period that approximates the expected term of the option, and the Company’s expected dividend yield. The Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies with similar characteristics including market capitalization, stage of development, therapeutic focus and certain financial measures. The expected volatility has been determined using an average of the historical volatility measures of this group of guideline companies. The expected option term was calculated based on the simplified method for awards with only service based vesting conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to develop an estimate based on participant***~~

~~***behavior. For awards with both performance and service based vesting conditions, the expected term has been determined using management’s best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, if any, and comparison to expected terms used by peers. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common shares; therefore, the expected dividend yield is assumed to be zero.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Prior to the consummation of the Reverse Recapitalization, because there was no public market for the Company’s common shares, the Board of Directors has determined the fair value of the Company’s common shares based on third-party valuations of the Company’s common shares. Initially, the estimated enterprise equity value of the Company was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Company’s various securities of its capital structure using an option pricing method, or OPM, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New***~~

~~***Roman;min-width:fit-content;">Significant assumptions used in the OPM to determine the fair value of common shares include volatility, discount for lack of marketability, and the expected timing of a future liquidity event such as an initial public offering (“IPO”), or sale of the Company in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios. In addition, the Company’s Board of Directors considered various objective and subjective factors to determine the fair value of the Company’s common shares as of each grant date, including the prices at which Old enGene sold shares of redeemable convertible preferred shares and the superior rights and preferences of the redeemable convertible preferred shares relative to its common shares at the time of each grant, external market conditions, the progress of the Company’s research and development programs, the Company’s financial position, including cash on hand, and its historical and forecasted performance and operating results, and the lack of an active public market for the Company’s common shares and redeemable convertible preferred shares, among other factors.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The assumptions underlying these valuations represented management’s best estimate, which involved inherent uncertainties and the application of management’s judgment and these valuations are sensitive to changes in the unobservable inputs. As a result, if the Company had used different assumptions or estimates or if there are changes to the unobservable inputs, the fair value of its common shares and share-based compensation expense could have been materially different.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-***~~

~~align:justify;">Subsequent to becoming a publicly traded Company upon the consummation of the Reverse Recapitalization, the fair value of common shares underlying equity awards is based on the market price of the Company’s common stock at the date of the grant.</p></div><div><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company’s share-based compensation expense is recorded in general and administrative and research and development expenses in the Company’s consolidated statements of operations and comprehensive loss.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Income Taxes</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company’s consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on differences between the consolidated financial statement carrying amounts and the tax basis of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available~~

~~evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Comprehensive Loss</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;">Comprehensive loss includes net loss as well as other changes in shareholders’ deficit that result from transactions and economic events other than those with shareholders. The Company’s comprehensive loss includes foreign currency translation.</p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Net Loss Per Share</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common shares. Net loss per share attributable to common shareholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company’s common shares and participating securities. Net loss attributable to common shareholders is allocated first based on dividend rights and then to common and preferred shareholders based on ownership interests on an as-converted basis as if all the earnings for the period had been distributed.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">When considering the impact of the convertible***~~

~~equity instruments, diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred shareholders and warrant holders based on dividend rights and then to common and preferred shareholders and warrant holders based on ownership interests. As preferred shares have converted to common shares at the completion of Reverse Recapitalization, the abovementioned policy is only applicable for the year ended October 31, 2023. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, and the potential issuance of common shares upon the conversion of the convertible notes. Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders is generally the same as basic net loss per share attributable to common shareholders because dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. See Note 15, Net Loss per Share, for further detail.</p></div><div><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Deferred Transaction Costs </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-~~

~~***content;">The Company capitalized certain legal, professional accounting and other third-party fees that were directly associated with the Reverse Recapitalization and PIPE Financing as deferred transaction costs until such transaction was consummated. After the consummation of such transaction, these costs were recorded within equity as a reduction of the common share and warrants value within additional paid in capital, for both instruments issued and assumed to shareholders of FEAC and to PIPE financing investors, were allocated to each on a relative fair value basis. The Company incurred a total of $11.3 million of transaction costs as part of the Reverse Recapitalization and PIPE Financing. In addition, transaction costs of $ 0.8 million related to the issuance of the April 2023 Notes and the May 2023 Notes for which the fair value option of accounting was elected and those allocated to the liability classified </p></div><div***~~

~~style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">warrants issued as part of the 2023 Financing are not deferred and are included in general and administrative expenses in the Company’s consolidated statements of operations and comprehensive loss.</p></div> <div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Government Assistance Programs for Research and Development Expenditures</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company was eligible to claim Canadian federal and provincial tax credits as a Canadian controlled private corporation (“CCPC”) on eligible scientific research and experimental development (“SR&amp;ED”) expenditures through September 2023, at which time the Company lost its status as a CCPC. In addition, effective for fiscal 2023, the Company’s maximum refundable tax credits were reduced due to the Company’s taxable capital, as defined in the Income Tax Act<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-~~

~~width:fit-content;"> (Canada), which reduction in credits has been recorded in the fourth quarter. The Canadian federal government offers a tax incentive to companies performing research and development activities in Canada and this tax incentive can be refunded or used to reduce federal income taxes in Canada otherwise payable. Such credits, if not refunded or used in the year earned, can be carried forward for a period of twenty years. The Quebec provincial government offers a similar refundable incentive. The investment tax credits recorded are based on management’s estimates of amounts expected to be recovered and are subject to audit by the taxation authorities, the resulting adjustments of which could be significant. Following the loss of CCPC status, the Company’s SR&amp;ED tax credits will be earned at a lower rate and some will no longer be refundable. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Amounts received or receivable resulting from government assistance programs, including investment tax credits for SR&amp;ED, are recognized when there is reasonable assurance that the amount will be received, and all attached conditions will be complied with. Reimbursements of eligible SR&amp;ED expenditures pursuant to government assistance programs are received in cash. The amounts receivable are recorded as reductions of research and development costs when the related costs have been incurred and there is reasonable assurance regarding collection of the claim. During the years ended October 31, 2024 and 2023, the Company recorded $<span~~

~~***style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">0.4 million and $1.1 million, respectively, as a reduction of research and development expense associated with SR&amp;ED investment tax credits. </p></div><div><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Recently Adopted Accounting Pronouncements </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). This new standard changes the impairment model for most financial assets and certain other instruments. Entities will be required to use a model that will result in the earlier recognition of allowances for losses for trade and other receivables,***~~

~~held-to-maturity debt securities, loans, and other instruments. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. In November 2019, the FASB issued ASU 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) (“ASC 2019-10”), which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, for entities meeting the definition of a smaller reporting company. The Company adopted ASU 2016-13 effective November 1, 2023 and the adoption did not have a material impact on the consolidated financial statements.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Recently~~

~~***Issued Accounting Pronouncements – Not Yet Adopted </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In June 2022, the FASB issued ASU No. 2022-03, Fair Value Measurement (Topic 820) – Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions, which amends guidance in ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company does not expect that the adoption of this standard will have a material impact on its financial statements and related disclosures.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which requires incremental disclosure of segment information on an interim and annual basis. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application to all prior periods presented in the financial statements is required for public entities. The Company is currently evaluating the impact of the guidance on the financial***~~

~~statements disclosures.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires entities to disclose additional information about specific expense categories in the notes to the financial statements. The ASU is effective for annual periods beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is </p></div><div style="font-size:10pt;font-family:Times New Roman;"><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the effect of this update on its consolidated financial statements and related disclosures.</p></div><p style="font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Basis of Presentation</p><p style="text-~~

~~***indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The accompanying consolidated financial statements are prepared in accordance with U.S. GAAP and include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and as amended by Accounting Standards Updates (“ASU’s”) of the Financial Accounting Standards Board (“FASB”).</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:6pt;text-align:justify;">The consolidated financial statements are expressed in US dollars. The consolidated financial statements have been prepared on a historical cost basis, except for items that are required to be accounted for at fair value.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">As the merger with FEAC has been accounted for as a reverse recapitalization, the historical operations of the Company represent that of Old enGene which is the accounting predecessor. The number of common shares, net loss per common share, the number of warrants to purchase common shares, and the number of stock options and the related exercise prices of the stock options issued and outstanding prior to the Reverse Recapitalization have been retrospectively restated to reflect the Exchange Ratio of approximately ***~~

~~0.18048 established in the Merger Agreement. Please see Note 3, Reverse Recapitalization for additional information.</p>0.0018048<p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Use of Estimates</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The preparation of the Company’s consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include but are not limited to the accrual of research and development expenses, share-based payments and the recoverability of investment tax credits receivable and, in addition, for fiscal 2023: the valuations of common shares, redeemable convertible preferred shares, warrants to purchase redeemable convertible preferred shares, convertible debentures, and embedded derivatives on convertible debt. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Actual results could differ from those estimates and such~~

~~differences may be material to the consolidated financial statements.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Segment Information</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:6pt;text-align:justify;">Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates as a single business segment focused on research, discovery, and clinical development of human genetic medicine products. The majority of the Company’s tangible assets are held in Canada.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Risk of Concentrations of Credit and Off-Balance Sheet Risk</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits. Management believes that the Company is~~

~~not currently exposed to significant credit risk as the Company’s deposits were held in custody at third-party financial institutions.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company's investment policy limits investments to certain types of securities issued by the U.S. Government and its agencies, as well as institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of marketable securities to the extent recorded on the Consolidated Balance Sheets. As of October 31, 2024 and 2023, the Company had no off-balance sheet concentrations of credit risk.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-~~

~~***bottom:0;text-align:justify;">The Company is dependent on third-party CDMOs and CRO with whom it does business. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements of active pharmaceutical ingredients and formulated drugs in order to perform research and development activities in its programs. The Company also relies on a limited number of third-party CROs to perform research and development activities on its behalf. These programs could be adversely affected by significant interruption from these providers.</p>As of October 31, 2024 and 2023, the Company had no off-balance sheet concentrations of credit risk00<p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Cash and Cash Equivalents</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company considers all short-term, highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company’s cash and cash equivalents include bank balances, demand deposits and other short-term, highly liquid investments. The fair value of cash and cash equivalents approximate the amortized cost. The Company had $173.0<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-***~~

~~content;"> million of cash and cash equivalents as of October 31, 2024 and $81.5 million of cash as of October 31, 2023.</p>17300000081500000<p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Marketable securities</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company's marketable securities are maintained by investment managers and consist of money market funds, U.S. government agency securities and treasuries. If the remaining contractual maturity is within one year from the balance sheet date, the marketable securities are classified as current and otherwise, they are classified as non-current assets.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Investment in marketable securities is classified as available-for-sale and is reported at fair value using quoted prices in active markets for similar~~

~~securities. Unrealized gains and losses on available-for-sale securities are reported as a separate component of stockholders' equity in other comprehensive loss. Premium or discounts from par value are amortized to investment income over the life of the underlying investment.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company periodically evaluates the need for an allowance for credit losses. The evaluation includes consideration of several qualitative and quantitative factors, including whether it has plans to sell the security, whether it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis, and if the entity has the ability and intent to hold the security to maturity, and the portion of any unrealized loss that is the result of a credit loss. Factors considered in making these evaluations include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, expected cash flows from securities, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and the Company's strategy and intentions for holding the marketable security.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">When the fair value is below the amortized cost of the asset, an estimate of expected credit losses is made. The Company records credit losses in the consolidated statements of operations and comprehensive loss as a credit loss expense within other income, net, which is limited to the difference between the fair value~~

~~and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale securities.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Accrued interest receivable related to the Company's available-for-sale securities is presented within prepaids and other current assets on the Company's consolidated balance sheets. The Company has elected the practical expedient available to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivable associated with its marketable securities.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Property and Equipment</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Property and equipment are comprised mainly of research and development equipment, computer hardware and software, office furniture and equipment, and leasehold improvements. Property and equipment are stated at cost less accumulated depreciation and accumulated impairment~~

~~***Roman;margin-bottom:0;text-align:justify;"> </p><p style="text-indent:4.533%;font-size:10pt;margin-top:2pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheet and any resulting gains or losses are included in the consolidated statements of operations and comprehensive loss in the period of disposal.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company reviews long-lived assets, such as property and equipment, for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. If indicators of impairment are present, the assets are tested for recoverability by comparing the carrying amount of the assets to the related estimated future undiscounted cash flows that the assets are expected to generate. If the expected undiscounted cash flows are less than the carrying value of the assets, then the assets are considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows. To date, no such impairment losses have been recorded.</p>Depreciation expense is recognized using the***~~

~~indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company adopted FASB ASC 842 with an effective date of November 1, 2019, using the modified retrospective transition approach which uses the effective date as the date of initial application. In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use (“ROU”) asset and a lease liability on the consolidated balance sheet for all leases with an initial lease term of greater than 12 months. The Company has elected to not recognize leases with a lease term of 12 months or less on the balance sheet.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities, and other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-~~

~~***family:Times New Roman;margin-bottom:0;text-align:justify;">Lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Fair Value Measurements of Financial Instruments</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities***~~

~~carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable: </p><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6.3pt;justify-content:flex-start;align-items:baseline;margin-bottom:6pt;min-width:4.537%;text-align:left;">o<div style="width:100%;display:inline;">Level 1—Quoted prices in active markets for identical assets or liabilities.</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6.5pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;margin-right:10.269%;min-width:4.537%;text-align:justify;">o<div style="width:100%;display:inline;">Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6.1pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;margin-right:12.13%;min-width:4.537%;text-align:justify;"><span~~

~~style="color:#231f20;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:4.7521786492374725%;word-break:keep-all;display:inline-flex;justify-content:flex-start;">o<div style="width:100%;display:inline;">Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.</div></div><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">At October 31, 2024, financial instruments measured at fair value on a recurring basis include marketable securities (see Note 5, Marketable Securities, and Note 4, Fair Value Measurements). The carrying amounts of accounts payable and accrued expenses approximate their fair~~

~~values due to their short-term nature.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;margin-right:12.13%;text-align:justify;">Fair Value Option</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company elected the fair value option of accounting of ASC 825 for all convertible debentures issued in fiscal 2023 from their issuance date in order to not have to bifurcate any embedded derivatives in accordance with ASC 815. The notes for which the fair value option of accounting is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the notes accounted for at fair value, which include accrued interest, if any, are recorded as a component of other expense (income), net in the consolidated statement of operations and comprehensive loss. The Company has not elected to present interest expense separately from changes in fair value and therefore will not present interest expense associated with the notes. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income. During the year ended October 31, 2023, the Company did not record any changes in fair value related to instrument-specific credit risk. All costs associated with the issuance of the convertible debentures accounted for using the fair value option were expensed upon issuance.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;margin-right:12.13%;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-weight:bold;font-size:10pt;font-family:Times New~~

~~Roman;font-style:italic;min-width:fit-content;">Debt Issuance Costs</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company capitalizes certain legal, accounting, and other third-party fees that are directly associated with the issuance of debt not accounted for using the fair value option as debt issuance costs. Debt issuance costs are recorded as a direct reduction of the carrying amount of the associated debt on the Company’s consolidated balance sheets and amortized as interest expense on the Company’s consolidated statements of operations and comprehensive loss using the effective interest method.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;margin-right:12.13%;text-align:justify;">Convertible Debenture Embedded Derivative Liabilities</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company’s convertible debentures contained certain features that meet the definition of embedded derivatives requiring bifurcation from the convertible debenture instrument, for which the fair value option was not elected, as a separate compound derivative. The convertible debenture embedded derivative liabilities are initially measured at fair value on issuance and is subject to remeasurement at each reporting period with changes in fair value recognized in the change in fair value of derivative liabilities, net in the consolidated statements of operations and comprehensive loss.<span style="color:#000000;white-space:pre-~~

~~wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;"> </p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;margin-right:12.13%;text-align:justify;">Common Share and Preferred Share Warrants</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company accounts for its common share warrants and redeemable convertible preferred shares warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants that have been determined to be classified as liabilities are recorded on the consolidated balance sheets at their fair value on the date of issuance and remeasured to fair value at each reporting period, with the changes in fair value recognized in the change in fair value of warrant liabilities, net in the consolidated statements of operations and comprehensive loss. The Company adjusted the liability for changes in the fair value of these warrants until the earlier of the exercise of the warrants, the expiration of the warrants, or until such time as the warrants were no longer considered liability.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Convertible Debentures</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-~~

~~size:10pt;font-family:Times New Roman;min-width:fit-content;">The Company’s 2022 Notes (as defined in Note 9, Notes Payable) are convertible debentures that consist of a debt instrument, a minimum interest obligation, and a share conversion feature. Certain of the convertible debentures issued by the Company also included warrants to purchase redeemable convertible preferred shares, which were classified as liabilities. The Company identified embedded derivatives related to certain share conversion and repayment features within the convertible notes that required bifurcation as a single compound derivative instrument. At inception, the Company utilized the residual method to determine the value of the debt instrument based on the difference between gross proceeds and the estimated fair value of the embedded derivative and any warrants that were issued. The debt instrument is accounted for using the amortized cost method. The discounts on debt resulting from any issuance costs, embedded derivatives and warrants are amortized over the life of the debt using the effective interest method. The issuance costs allocated to the embedded derivatives and warrants are expensed at inception.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Research and Development Expenses</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Research and development expenses are comprised primarily of costs incurred for our drug discovery efforts and development of our product candidates. These expenses include salaries, employee benefits, and share-based compensation expense for our research and development~~

~~personnel, materials, supplies, depreciation on and maintenance of research equipment, the cost of services provided by outside CROs and consultants to conduct research and development activities including costs of clinical trials and manufacturing, and the allocable portions of facility costs, such as rent, utilities, and general support services. All costs associated with research and development are expensed as incurred. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Management estimates the Company’s accrued research and development expenses as of each balance sheet date in the Company’s financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services are deferred and recognized as expense in the period that the related goods are consumed or services are performed.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Patent Costs</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">All patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the recovery of the expenditure. Patent-related costs are~~

~~classified as general and administrative expenses within the Company’s consolidated statements of operations.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Share-Based Compensation</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company has an incentive equity plan (the “2023 Incentive Equity Plan” or the “2023 Plan”), whereby employees render services as consideration for equity instruments. The 2023 Plan was adopted on October 31, 2023 upon the completion of the Reverse Recapitalization and superseded Old enGene’s employee stock option plan (the “ESOP”) and equity incentive plan (the “EIP”) (collectively, the “Old Plans”). The Company measures all share-based awards granted to employees, officers, directors and non-employees based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures of its share-based awards as they occur. The Company issues share-based awards with service-based vesting conditions and awards with both performance and service-based vesting conditions. For share-based awards with service-based vesting conditions, the Company records the expense using the straight-line method including when such awards have graded vesting. For share-based awards with both performance and service-based vesting conditions, the Company records the expense using an accelerated attribution method, once the performance conditions are considered probable of being achieved, using management’s best estimate.</p><p~~

~~style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the Company’s common shares, expected share price volatility, the expected term of the award, the risk-free interest rate for a period that approximates the expected term of the option, and the Company’s expected dividend yield. The Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies with similar characteristics including market capitalization, stage of development, therapeutic focus and certain financial measures. The expected volatility has been determined using an average of the historical volatility measures of this group of guideline companies. The expected option term was calculated based on the simplified method for awards with only service based vesting conditions, which uses the midpoint between the vesting date and the contractual term, as the Company does not have sufficient historical data to develop an estimate based on participant behavior. For awards with both performance and service based vesting conditions, the expected term has been determined using management’s best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, if any, and comparison to expected terms used by peers. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common shares; therefore, the expected~~

~~dividend yield is assumed to be zero.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Prior to the consummation of the Reverse Recapitalization, because there was no public market for the Company’s common shares, the Board of Directors has determined the fair value of the Company’s common shares based on third-party valuations of the Company’s common shares. Initially, the estimated enterprise equity value of the Company was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Company’s various securities of its capital structure using an option pricing method, or OPM, and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Significant assumptions used in the OPM to determine the fair value of common shares include volatility, discount for lack of marketability, and the expected timing of a future liquidity event such as an initial public offering (“IPO”), or sale of the Company in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios. In addition, the Company’s Board of Directors considered various objective and subjective factors to determine the fair value of the Company’s common shares as of each grant date, including the prices at which Old enGene sold shares of redeemable convertible preferred shares and~~

~~***the superior rights and preferences of the redeemable convertible preferred shares relative to its common shares at the time of each grant, external market conditions, the progress of the Company’s research and development programs, the Company’s financial position, including cash on hand, and its historical and forecasted performance and operating results, and the lack of an active public market for the Company’s common shares and redeemable convertible preferred shares, among other factors.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The assumptions underlying these valuations represented management’s best estimate, which involved inherent uncertainties and the application of management’s judgment and these valuations are sensitive to changes in the unobservable inputs. As a result, if the Company had used different assumptions or estimates or if there are changes to the unobservable inputs, the fair value of its common shares and share-based compensation expense could have been materially different.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Subsequent to becoming a publicly traded Company upon the consummation of the Reverse Recapitalization, the fair value of common shares underlying equity awards is based on the market price of the Company’s common stock at the date of the grant. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company’s share-based compensation***~~

~~expense is recorded in general and administrative and research and development expenses in the Company’s consolidated statements of operations and comprehensive loss.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Income Taxes</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company’s consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on differences between the consolidated financial statement carrying amounts and the tax basis of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-~~

~~than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.</p>0.50<p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Comprehensive Loss</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Comprehensive loss includes net loss as well as other changes in shareholders' deficit that result from transactions and economic events other than those with shareholders. The Company's comprehensive loss includes foreign currency translation.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Net Loss Per Share</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;">Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common shares. Net loss per share attributable to common shareholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. Net loss attributable to common shareholders is allocated first based on dividend rights and then to common and preferred shareholders based on ownership interests on an as-converted basis as if all the earnings for the period had been distributed.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">When considering the impact of the convertible equity instruments, diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred shareholders and warrant holders based on dividend rights and then to common and preferred shareholders and warrant holders based on ownership interests. As preferred shares have converted to common shares at the completion of Reverse Recapitalization, the abovementioned policy is only applicable for the year ended October 31, 2023. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, and the potential issuance of common shares upon the conversion of the convertible notes. Common stock equivalent shares are excluded from the***~~

~~computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders is generally the same as basic net loss per share attributable to common shareholders because dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. See Note 15, Net Loss per Share, for further detail.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">Deferred Transaction Costs </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company capitalized certain legal, professional accounting and other third-party fees that were directly associated with the Reverse Recapitalization and PIPE Financing as deferred transaction costs until such transaction was consummated. After the consummation of such transaction, these costs were recorded within equity as a reduction of the common share and warrants value within additional paid in capital, for both instruments issued and assumed to shareholders of FEAC and to PIPE financing investors, were allocated to each on a relative fair value basis. The Company incurred a total of $11.3<span style="color:#000000;white-space:pre-wrap;font-~~

~~size:10pt;font-family:Times New Roman;min-width:fit-content;"> million of transaction costs as part of the Reverse Recapitalization and PIPE Financing. In addition, transaction costs of $ 0.8 million related to the issuance of the April 2023 Notes and the May 2023 Notes for which the fair value option of accounting was elected and those allocated to the liability classified </p><p style="font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">warrants issued as part of the 2023 Financing are not deferred and are included in general and administrative expenses in the Company’s consolidated statements of operations and comprehensive loss. </p>11300000800000<p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;"><span style="color:#000000;white-space:pre-wrap;font-weight:bold;font-size:10pt;font-family:Times New~~

~~*Roman;font-style:italic;min-width:fit-content;">Government Assistance Programs for Research and Development Expenditures</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company was eligible to claim Canadian federal and provincial tax credits as a Canadian controlled private corporation (“CCPC”) on eligible scientific research and experimental development (“SR&amp;ED”) expenditures through September 2023, at which time the Company lost its status as a CCPC. In addition, effective for fiscal 2023, the Company’s maximum refundable tax credits were reduced due to the Company’s taxable capital, as defined in the Income Tax Act (Canada), which reduction in credits has been recorded in the fourth quarter. The Canadian federal government offers a tax incentive to companies performing research and development activities in Canada and this tax incentive can be refunded or used to reduce federal income taxes in Canada otherwise payable. Such credits, if not refunded or used in the year earned, can be carried forward for a period of twenty years. The Quebec provincial government offers a similar refundable incentive. The investment tax credits recorded are based on management’s estimates of amounts expected to be recovered and are subject to audit by the taxation authorities, the resulting adjustments of which could be significant. Following the loss of CCPC status, the Company’s SR&amp;ED tax credits will be earned at a lower rate and some will no longer be refundable. <span style="color:#000000;white-space:pre-wrap;font-*~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;"> </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Amounts received or receivable resulting from government assistance programs, including investment tax credits for SR&amp;ED, are recognized when there is reasonable assurance that the amount will be received, and all attached conditions will be complied with. Reimbursements of eligible SR&amp;ED expenditures pursuant to government assistance programs are received in cash. The amounts receivable are recorded as reductions of research and development costs when the related costs have been incurred and there is reasonable assurance regarding collection of the claim. During the years ended October 31, 2024 and 2023, the Company recorded $0.4 million and $1.1 million, respectively, as a reduction of research and development expense associated with SR&amp;ED investment tax credits. </p>4000001100000<p style="font-***~~

~~size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Recently Adopted Accounting Pronouncements </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). This new standard changes the impairment model for most financial assets and certain other instruments. Entities will be required to use a model that will result in the earlier recognition of allowances for losses for trade and other receivables, held-to-maturity debt securities, loans, and other instruments. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than reductions in the amortized cost of the securities. In November 2019, the FASB issued ASU 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) (“ASC 2019-10”), which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, for entities meeting the definition of a smaller reporting company. The Company adopted<span style="color:#000000;white-space:pre-wrap;font-~~

~~size:10pt;font-family:Times New Roman;min-width:fit-content;"> ASU 2016-13 effective November 1, 2023 and the adoption did not have a material impact on the consolidated financial statements.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Recently Issued Accounting Pronouncements – Not Yet Adopted </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In June 2022, the FASB issued ASU No. 2022-03, Fair Value Measurement (Topic 820) – Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions, which amends guidance in ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and introduces new disclosure requirements for equity securities subject to contractual~~

~~sale restrictions that are measured at fair value. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company does not expect that the adoption of this standard will have a material impact on its financial statements and related disclosures.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which requires incremental disclosure of segment information on an interim and annual basis. This ASU is effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Retrospective application to all prior periods presented in the financial statements is required for public entities. The Company is currently evaluating the impact of the guidance on the financial statements disclosures.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires entities to disclose additional information about specific expense categories in the notes to the financial statements. The ASU is effective for annual periods beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15,~~

~~***2027. Early adoption is </p><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the effect of this update on its consolidated financial statements and related disclosures.</p>true2023-11-01true<p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">3. Reverse Recapitalization</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On October 31, 2023 (the “Closing Date”), FEAC, Old enGene, and the Company consummated the merger pursuant to the Merger Agreement, dated as of May 16, 2023. As a result of the Reverse Recapitalization, the Company became a publicly traded***~~

~~***company, with old enGene, a subsidiary of the Company, continuing the existing business operations. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">At the effective time of the Reverse Recapitalization: </p><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;min-width:4.537%;text-align:justify;">•<div style="width:100%;display:inline;">each outstanding share of Old enGene common stock was exchanged for the Company’s common shares at the Exchange Ratio;</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;min-width:4.537%;text-align:justify;">•<div style="width:100%;display:inline;">each share of Old enGene’s redeemable***~~

~~***convertible preferred shares outstanding immediately prior to the close of the Reverse Recapitalization was exchanged for shares of the Company’s common shares based on the same Exchange Ratio, with no dividends or distributions being declared or paid on Old enGene’s redeemable convertible preferred shares;</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;min-width:4.537%;text-align:justify;">•<div style="width:100%;display:inline;">the 2022 Notes and May 2023 Notes (each as defined in Note 9, Notes Payable) of Old enGene’s existing convertible notes outstanding immediately prior to the close of the Reverse Recapitalization were converted to Old enGene common shares at the conversion ratio in place at the time of conversion and were exchanged for shares of the Company at the Exchange Ratio; and</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;min-width:4.537%;text-align:justify;">•<div style="width:100%;display:inline;">each outstanding option to purchase Old enGene common stock became fully vested and converted into an option to purchase a number of the Company’s common shares equal to the number of shares of old***~~

~~***enGene common stock subject to such option multiplied by the Exchange Ratio, rounded down to the nearest whole share, at an exercise price per share equal to the current exercise price per share for such option divided by the Exchange Ratio, rounded up to the nearest whole cent;</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;min-width:4.537%;text-align:justify;">•<div style="width:100%;display:inline;">all of Old enGene’s outstanding warrants exercisable for common shares in Old enGene were exchanged for warrants exercisable for the Company’s common shares using the Exchange Ratio, with the warrants maintaining the same terms and conditions;</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;min-width:4.537%;text-align:justify;">•<div style="width:100%;display:inline;">all of Old enGene’s existing outstanding Class C warrants outstanding at the time of the Reverse Recapitalization were terminated; and</div></div><div class="item-list-element-wrapper" style="margin-left:4.528%;display:flex;margin-top:6pt;justify-content:flex-start;align-items:baseline;margin-bottom:0;min-width:4.537%;text-***~~

~~***align:justify;">•<div style="width:100%;display:inline;"> all outstanding FEAC Shares of 3,670,927 held by FEAC Sponsor and shareholders were converted into the same number of the Company’s common shares, and outstanding FEAC warrants of 5,029,444 held by FEAC warrant holders were converted into the same number of warrants to purchase one share of the Company’s common shares. </div></div> <p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Upon the close of the Reverse Recapitalization, 13,091,608 common shares of the Company were issued to the Old enGene’s equity and convertible note holders, <span style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-***~~

~~width:fit-content;">2,679,432 common share warrants of the Company were issued to Old enGene’s warrant holders, and 2,706,941 common share options of the Company were issued to Old enGene’s share option holders. </p><p style="text-indent:4.564%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;margin-right:0.667%;text-align:justify;">In connection with the Merger Agreement, FEAC, the Company, and PIPE Investors entered into Subscription Agreements pursuant to which, the PIPE Investors have agreed to purchase the Company’s shares and warrants for an aggregate commitment amount of $56.9 million. As part of the PIPE Financing, the Company issued <span~~

~~style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">6,435,441 shares of the Company’s common shares and 2,702,791 warrants to purchase the Company’s common shares for an aggregate purchase price equal to $56.9 million on October 31, 2023. The common shares and warrants issued as part of the PIPE Financing were determined to be equity classified. The proceeds were allocated between the common shares and warrants on a relative fair value basis, taking into consideration the quoted market price of the FEAC common shares and warrants on the close of the market on October 31, 2023, resulting in $56.1 million being allocated to the common shares and $0.8 million being allocated to~~

~~the warrants. In connection with the Merger Agreement, FEAC, the FEAC Sponsor, Forbion Growth Opportunities Fund I Cooperatief U.A. and the other holders of FEAC Class B Shares, Old enGene, the Company and the other parties named therein entered into the Side Letter Agreements, pursuant to which the FEAC Sponsor agreed to surrender and in effect issue to PIPE Investors FEAC Class B shares and FEAC private placement warrants, immediately prior to the closing of the Reverse Recapitalization. Immediately following the Reverse Recapitalization and the PIPE Financing, the Company had 23,197,976 common shares and 10,411,641 warrants outstanding.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On October 31, 2023, as part of the close of Reverse Recapitalization, the Company received proceeds of $<span style="font-size:10pt;font-family:Times~~

~~***New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">7.4 million, from the FEAC trust account, net of the redemption payment to FEAC’s public shareholders and cash paid from the trust for FEAC expenses. Additionally, the Company received proceeds of approximately $56.9 million from the PIPE Financing. Upon the closing of the Reverse Recapitalization and PIPE Financing, the Company incurred $6.0 million in transaction costs, which was withheld from the proceeds received. The Company incurred a total of $11.1 million of transaction costs associated with the Reverse Recapitalization and PIPE Financing, of which $5.1 million was previously deferred by the Company and netted against the proceeds upon close. The transaction costs were allocated to the common shares***~~

~~top:2pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The total transaction costs of $11.1 million were related to third-party legal, accounting services and other professional services to consummate the Reverse Recapitalization and the PIPE Financing incurred by Old enGene. These transaction costs are allocated between common shares and additional paid-in capital, based on the relative fair value of the common shares and warrants issued upon the close of the Reverse Recapitalization, on the Company's consolidated balance sheet as the Company's common shares have no par value.</p><div style="font-size:10pt;font-family:Times New Roman;"><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The following table summarizes the number of common shares outstanding immediately following the consummation of the Reverse Recapitalization and PIPE Financing transaction:</p><p style="text-indent:4.533%;font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:0;text-align:justify;"> </p> <table style="margin-left:auto;border-spacing:0;table-layout:auto;width:60.0%;border-collapse:separate;margin-right:auto;"> <tr style="visibility:collapse;"> <td style="width:77.8%;box-sizing:content-box;"></td> <td style="width:1.667%;box-sizing:content-box;"></td> <td~~

~~Roman;margin-bottom:0;margin-right:0.009722222222222222in;text-align:right;">—</p></td> <td style="padding-top:0in;white-space:nowrap;vertical-align:bottom;padding-bottom:0in;border-bottom:2.25pt double #ffffff03;"><p style="font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:0;text-align:left;"> </p></td> </tr> </table></div><p style="font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:0;text-align:justify;"> </p><p id="bookmark_id_4d34og8" style="text-indent:4.533%;font-size:10pt;margin-top:2pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">As of October 31, 2024, the Company classified its government agency marketable securities as Level 2 within the valuation hierarchy. The Company estimates the fair value of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly to estimate fair value. These inputs include market pricing based on real time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs.</p><p style="text-indent:4.533%;font-size:10pt;margin-~~

~~top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">During the years ended October 31, 2024 and 2023, there were no transfers or reclassifications between fair value measure levels of assets or liabilities. The carrying values of all other financial current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Convertible Debentures Embedded Derivative Liabilities </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Prior to the Reverse Recapitalization, the Company’s convertible debentures contained equity conversion options, and certain repayment features, that have been identified as a single compound embedded derivative requiring bifurcation from the host contract for the convertible debentures for which the fair value has~~

~~***not been elected. The Company estimated the fair value of the convertible debenture embedded derivative liabilities on issuance using a probability weighted scenario expected return model. The estimated probability and timing of underlying events triggering the conversion and liquidity repayment features and probability of exercise of the extension features within the convertible debentures as well as discount rates, volatility and share prices are inputs used to determine the estimated fair value of the embedded derivative. </p><div style="font-size:10pt;font-family:Times New Roman;"><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The assumptions ranges that the Company used to determine the fair value of the convertible debentures embedded derivative liabilities for the 2022 Notes and BDC Notes that were outstanding as of each respective period (refer to Note 9, Notes Payable) were as follows:</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"> </p> <table style="margin-left:auto;border-spacing:0;table-layout:auto;width:70.0%;border-collapse:separate;margin-right:auto;"> <tr style="visibility:collapse;"> <td style="width:80.076%;box-sizing:content-box;"></td> <td style="width:1.78%;box-sizing:content-box;"></td> <td style="width:1%;box-sizing:content-box;"></td> <td style="width:16.143%;box-sizing:content-box;"></td> <td style="width:1%;box-sizing:content-box;"></td> </tr> <tr style="height:8pt;background-color:#ffffff;word-break:break-word;white-space:pre-wrap;text-align:left;">***~~

~~left:4.533%;font-size:10pt;margin-top:2pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">* The probability represents the cumulated probabilities of conversion at various dates before maturity. The probability includes the probability of a SPAC transaction (which corresponds to a listing event for the 2022 Notes and to a liquidity event for the BDC Notes).</p><p style="margin-left:4.533%;font-size:10pt;margin-top:2pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">** Volatility and Class C Preferred share price is not applicable and expected time to scenario is 0.0 years as of October 31, 2023 as the 2022 Notes converted to shares upon the Reverse Recapitalization and the BDC Notes were repaid in full.</p><p style="margin-left:4.533%;font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:0;text-align:justify;">*** The liquidity price at the conversion of a listing event represents the conversion price of the 2022 Notes upon the merger with FEAC, and the fair value per common share at conversion of a listing event represents the quoted market price of the FEAC common shares on the close of the market on October 31, 2023, immediately prior to the settlement upon the completion of the Reverse Recapitalization.</p><p style="margin-~~

~~left:4.533%;font-size:10pt;margin-top:0;font-family:Times New Roman;margin-bottom:0;text-align:justify;">**** Discount rate includes credit risk, discount for lack of marketability and other factors considered in the model.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Upon the close of the Reverse Recapitalization the 2022 Notes were converted and exchanged for common shares of the Company, resulting in an extinguishment of the 2022 Notes and related embedded derivative liability. Further the BDC Note (as defined below) was repaid in full. See Note 3, Reverse Recapitalization and Note 10, Convertible Debentures for additional detail. Immediately prior to the conversion and exchange of the 2022 Notes as part of the Reverse Recapitalization, the embedded derivative was measured to a fair value of $24.8 million. Further immediately prior to the repayment of the BDC Note, the embedded derivative liability was measured to a fair value of $0.4 million.</p><div style="font-size:10pt;font-family:Times New Roman;"><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-~~

~~No change in fair value was recorded on the April 2023 Notes during the year ended October 31, 2023, given the close proximity between the issuance date of the notes and the repayment date. As of October 31, 2024 and 2023, the April 2023 Notes are no longer outstanding. </p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">May 2023 Notes</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company elected the fair value option of accounting for the May 2023 Notes. At issuance and for periods prior to the settlement of the May 2023 Notes, the Company estimated the fair value of the May 2023 Notes using a probability weighted scenario expected return model and was considered a Level 3 measurement per the fair value hierarchy. As part of the issuance of the May 2023 Notes, the Company also issued warrants which were determined to be freestanding, liability classified and measured at fair value. Refer below. The Company~~

~~*style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">*** Discount rate includes credit risk, discount for lack of marketability and other factors considered in the model.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Immediately prior to the conversion and exchange of the May 2023 Notes as part of the Reverse Recapitalization, the notes were remeasured to a fair value of $93.3 million. The fair value immediately prior to the settlement was determined using the quoted market price of $21.70 per share for the FEAC common shares on the close of business on October 31, 2023, which was determined to be fair value of the common share on settlement, and considering the 4,298,463 shares of the Company issued to the holders of the May 2023 Notes upon the consummation of the Reverse Recapitalization.<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-*~~

~~***style="white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;"> </p><p style="font-size:10pt;margin-top:8pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Warrant Liabilities </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Prior to the consummation of the Reverse Recapitalization, Old enGene issued warrants to purchase redeemable convertible preferred shares as part of the issuance of certain redeemable convertible preferred shares, convertible debentures, and the term loan (the “Preferred Share Warrants”). Upon the close of the Reverse Recapitalization, the Preferred Share Warrants were surrendered for no consideration and the fair value was determined to be zero. The Company estimated the fair value of its Preferred Share Warrant liabilities using a Modified Black-Scholes option-pricing model, which included assumptions that are based on the individual characteristics of the Preferred Share Warrants on the valuation date, and assumptions related to the fair value of the underlying redeemable convertible preferred shares, expected volatility, expected life, dividends, risk-free interest rate and discount for***~~

~~lack of marketability (“DLOM”). Due to the nature of these inputs, the Preferred Share Warrants are considered a Level 3 liability. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The weighted average expected life of the Preferred Share Warrants was estimated based on the weighting of scenarios considering the probability of different terms up to the contractual term of 10 years in light of the expected timing of a future exit event, which includes a SPAC transaction. The Company determines the expected volatility based on an analysis of reported data for a group of guideline companies that have issued instruments with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. The risk-free interest rate is determined by reference to the Canadian treasury yield curve in effect at the time of measurement of the warrant liabilities for time periods approximately equal to the weighted average expected life of the warrants. The Company has not paid, and did not anticipate paying, cash dividends on its redeemable convertible preferred shares; therefore, the expected dividend yield is assumed to be zero.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span~~

~~***style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">Because there was no public market for the underlying redeemable convertible preferred shares, the Company determined their fair value based on third-party valuations. Initially, the estimated enterprise equity value of the Company was determined using a market approach and/or cost approach by considering the weighting of scenarios estimated using a back-solve method based on recent financing transactions of the Company. This value was then allocated towards the Company's various securities of its capital structure using an option pricing method, or "OPM", and a waterfall approach based on the order of the superiority of the rights and preferences of the various securities relative to one another. Significant assumptions used in the OPM to determine the fair value of redeemable convertible preferred shares include volatility, DLOM, and the expected timing of a future liquidity event such as an IPO, SPAC transaction or sale of the Company, in light of prevailing market conditions. This valuation process creates a range of equity values both between and within scenarios.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In addition to considering the results of these valuations, the Company considered various objective and subjective factors to determine the fair value of the Company's preferred shares as of each valuation date, including the prices at which the Company sold redeemable convertible preferred in the most recent***~~

~~transactions, external market conditions, the progress of the Company's research and development programs, the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results, and the lack of an active public market for the Company's redeemable convertible preferred shares, among other factors.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:2pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"> </p><p style="text-indent:4.533%;font-size:10pt;margin-top:2pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The warrants issued by Old enGene as part of the 2023 Financing (the “2023 Warrants”) were concluded to be freestanding, liability classified instruments upon issuance, which were subsequently reclassified to equity upon the consummation of the Reverse Recapitalization. See Note 10. The Company estimated the fair value of the 2023 Warrants based on the underlying quoted market price of the FEAC public warrants, prior to the close of the Reverse Recapitalization. The 2023 Warrants were classified as a Level 2 measurement given they are substantially similar to FEAC public warrants. The price used to value the 2023 Warrants as of the issuance date and immediately prior to the consummation of the Reverse Recapitalization was $0.53 and $0.74<span style="color:#231f20;white-~~

~~***size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">31 securities, 21 of which were in unrealized loss position. All investments in an unrealized loss position were in this position for less than 12 months. The Company does not intend to sell its investments before recovery of the amortized cost basis of its debt securities at maturity and no allowance for credit losses was recorded as of October 31, 2024 because the decline in fair value below amortized cost is not related to credit losses. Securities are evaluated at the end of each reporting period. The unrealized losses on U.S. Treasury and Government agency securities range from 0-1% of their amortized cos<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-***~~

~~content;"> </p></div>377300075900034750008140003831000613000824 style="font-size:10pt;margin-top:8pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">8. License Agreement and Clinical Research Organization</p><p style="margin-left:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">License Agreement – Nature Technology Corporation</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On April 10, 2020, the Company entered into a Non-Exclusive License Agreement (the "License Agreement") with Nature Technology Corporation ("NTC") whereby the Company licenses certain rights to NanoplasmidTM technology from NTC for commercialization. Under the terms of the License Agreement, NTC granted to the Company and its affiliates a non-exclusive, royalty-bearing, sublicensable license to research, have researched, develop, have developed, make, have made, use, have used, import, have imported, sell, offer to sell, and have sold or offered for sale any product in the defined license field. Unless terminated earlier, the NTC license agreement will continue until no valid claim of any licensed patent exists in any country.~~

~~The Company can voluntarily terminate the license agreement with prior notice to NTC.</p><p style="text-indent:6.667%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company paid NTC an initial, upfront fee of $50 thousand which was recorded as research and development expense upon entering into the License Agreement. Beginning on the first anniversary of the effective date of the License Agreement and on each subsequent anniversary, the Company is required to pay NTC a $50 thousand annual maintenance fee. The Company is also required to make a payment to NTC of $50 thousand upon assigning the License Agreement to a third party.</p><p style="text-indent:6.667%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The License Agreement provides for a one-time payment of $<span style="font-size:10pt;font-family:Times New~~

~~***Roman;color:#231f20;white-space:pre-wrap;min-width:fit-content;">50 thousand for the first dose of a milestone product, as defined in the License Agreement, in the first patient in a Phase 1 clinical trial or, if there is no Phase 1 clinical trial, in a Phase 2 clinical trial, as well as a one-time payment of $450 thousand upon regulatory approval of a milestone product by the U.S. Food and Drug Administration. The first milestone related to the first dose of a milestone product, was achieved during the year ended October 31, 2021. The second milestone, regulatory approval of a milestone product, has not yet been achieved as of the year ended October 31, 2024. The Company is also required to pay NTC a royalty percentage in the low single digits of the aggregate net product sales in a calendar year by the Company, its affiliates or sublicensees on a product-by-product and country-by-country basis, as long as the composition or use of the applicable product is covered by a valid claim in the country where the net sales occurred. Royalty obligations under the license agreement will continue until the expiration of the last valid claim of a licensed patent covering such licensed product in such country.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In the event that the Company or any of its affiliates or sublicensees manufactures any Good***~~

~~***Manufacturing Practice (“GMP”) lot of a product, then the Company or any such affiliate or sublicensee will be obligated to pay NTC an amount per manufactured gram of GMP (or its equivalent) lot of product, which varies based on the volume manufactured. The payment will expire on a product-by-product basis upon receipt of regulatory approval to market a product in any country in the licensed territory.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">During each of the years ended October 31, 2024 and 2023, the Company incurred $50 thousand of expenses related to the annual maintenance fee under the License Agreement which is recorded within research and development expenses. </p>500005000050000500004500005000050000<p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">9. Notes Payable </p><p style="font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">2021 Loan and Security Agreement</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New***~~

~~Roman;min-width:fit-content;">On December 30, 2021, the Company entered into a Loan and Security Agreement (the “Prior Loan Agreement”) with Hercules Capital, Inc. (“Hercules” or the “Lender”) for the issuance of a term loan facility with an aggregate principal amount of up to $20.0 million (the “Prior Term Loan”). The Prior Loan Agreement provided for (i) an initial term loan advance of $7.0 million, which closed on December 30, 2021, (ii) subject to the achievement of certain clinical milestones (“Clinical Milestone”), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $4.0 million from </p><p style="font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-~~

~~content;">the achievement of the Clinical Milestone through June 15, 2022, which was drawn in June 2022, and (iii) subject to the achievement of certain financial milestones ("Financial Milestone"), a right of the Company to request that the Lender make additional term loan advances to the Company in an aggregate principal amount of up to $9.0 million from achievement of the Financial Milestone through December 15, 2022, which was not achieved. The Company is required to pay an end of term fee ("Prior Term Loan End of Term Charge") equal to 6.35% of the aggregate principal amount of the Prior Term Loan advances upon repayment.</p> <p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Prior Term Loans were scheduled to mature on <span style="font-size:10pt;font-~~

~~***family:Times New Roman;">July 1, 2025, with no option for extension (the “Prior Term Loan Maturity Date”).</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Prior Term Loan accrued interest at an annual rate equal to the greater of (i) 8.25% plus the prime rate of interest as reported in the Wall Street Journal minus 3.25% and (ii) 8.25% provided, that, from and after the date the Company achieves the financial milestone, as defined within the agreement, the reference to 8.25<span style="color:#000000;white-space:pre-wrap;font-***~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;">% in clauses (i) and (ii) is reduced to 8.15%. Borrowings under the Prior Term Loan are repayable in monthly interest-only payments through June 2023. After the interest-only payment period, borrowings under the Prior Term Loan are repayable in equal monthly payments of principal and accrued interest until the Maturity Date. At the Company’s option, the Company may elect to prepay all, but not less than all, of the outstanding term loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% of the principal amount outstanding if the prepayment occurs in any of the first twelve months following the closing date of the last draw down; (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the closing date of the last draw down, but on or prior to twenty-four months following the closing date of the last draw down; and 1.0<span style="color:#000000;white-space:pre-wrap;font-***~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;">% of the principal amount outstanding at any time thereafter but prior to the Maturity Date.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In connection with the Prior Term Loan, the Company granted Hercules a security interest senior to any current and future debts and to any security interest, in all of the Company’s right, title, and interest in, to and under all of the Company’s property and other assets, and certain equity interests and accounts of Old enGene, subject to limited exceptions including the <br/>Company’s intellectual property. The Prior Loan Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The debt discount and issuance costs under the Prior Term Loan were accreted to the principal amount of debt and being amortized from the date of issuance through the Maturity Date to interest expense using the effective-interest rate method. The effective interest rate of the outstanding debt under the Prior Loan Agreement was approximately 18.3% as of October 31, 2023. </p><p style="text-***~~

~~indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company borrowed $11.0 million under the Prior Loan Agreement and incurred $1.1 million of debt discount and issuance costs inclusive of facilities fees, legal fees, Prior Term Loan End of Term Charge and initial fair value of the warrants under the Prior Term Loan.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Old Hercules Warrants</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Under the Prior Loan Agreement, the Company agreed to issue to Hercules warrants (the “Old Hercules Warrants”) to purchase a number of shares of Old enGene’s redeemable convertible preferred shares at the exercise price equal to 2.5<span style="color:#000000;white-space:pre-wrap;font-~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;">% of the aggregate amount of the Prior Term Loans that are funded, as such amounts are funded. On the first tranche closing, Old enGene issued a warrant to purchase 84,714 Class C Preferred Shares which were determined to have a fair value of $34 thousand upon issuance. On the second tranche closing, in June 2022, Old enGene issued an additional warrant to purchase 48,978 Class C Preferred Shares which were determined to have a fair value of $23 thousand upon issuance. The fair value of the Old Hercules Warrant values were initially recorded as a discount to the Prior Term Loan principal balance and are being amortized to interest expense using the effective interest method over the life of the Prior Term Loan. </p><p style="text-***~~

~~indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Old Hercules Warrants were initially exercisable for a period of ten years from the date of the issuance of each warrant at a per-share exercise price equal to $2.632 Canadian dollars, subject to certain adjustments as specified in the warrants. In addition, the Company has granted to the holders of the Old Hercules Warrants certain registration rights on a pari passu basis with the holders of outstanding preferred shares and warrants to purchase preferred shares.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company accounted for the warrants as a liability prior to the consummation of the Reverse Recapitalization since they were indexed to Old enGene's redeemable convertible preferred shares that were classified as temporary equity. The Company remeasured the fair value of the warrants at each reporting date with changes being recorded as a change in the fair value of the warrant liabilities.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-~~

~~***family:Times New Roman;margin-bottom:0;text-align:justify;">Upon the close of the Reverse Recapitalization, the Old Hercules Warrants, along with all other warrants to purchase shares of Old enGene's redeemable convertible preferred shares, were surrendered for no consideration.</p><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Amended Loan and Security Agreement</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On December 22, 2023 (the “Hercules Closing Date”), the Company entered into an amended and restated loan and security Agreement (the “Amended Loan Agreement”), with Hercules, as agent and lender, and the several banks and other financial institutions or entities from time to time parties thereto (with Hercules, the “Lenders”). The Amended Loan Agreement amends and restates in its entirety the Prior Loan Agreement with Hercules dated December 30, 2021.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">As of October 31, 2024, the Amended Loan Agreement provides for a term loan facility of up to $50.0<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-***~~

~~***content;"> million available in multiple tranches (the “Term Loan”), as follows: (i) an initial term loan advance (the “Tranche 1 Advance”) that was made on the Tranche 1 Advance closing of $22.5 million, approximately $8.6 million of which was applied to refinance in full the term loans outstanding under the Prior Loan Agreement, (ii) subject to the achievement of the specified Interim Milestone (the “Interim Milestone”), which includes no default or event of default, delivery of written notice to the Lenders that the Company has conducted an analysis of interim efficacy of data from the clinical evaluation of detalimogene in the Phase 2 clinical study, and satisfaction of certain other conditions precedent, a right of the Company to request that the Lenders make additional term loan advances to us in an aggregate principal amount of up to $7.5 million from the date of achievement of the Interim Milestone through the earlier of (x) 60<span style="color:#000000;white-space:pre-wrap;font-***~~

~~size:10pt;font-family:Times New Roman;min-width:fit-content;"> days following the achievement of the Interim Milestone and (y) March 31, 2025, and (iii) an uncommitted tranche subject to the Lenders’ investment committee approval and satisfaction of certain other conditions precedent (including payment of a 0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time up to and including the Amortization Date (defined below) that the Lenders make additional term loan advances to the Company in an aggregate principal amount of up to $20.0 million. The Company is required to pay upon the earlier of January 1, 2028 (the “Maturity Date”) or payment in full of the Term Loans, an end of term fee equal to <span~~

~~style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">5.50% of the aggregate principal amount of the Term Loans (the “End of Term Charge”). The Company is also required to pay on July 1, 2025 or, if earlier, the date the Company prepays the Term Loans, $0.7 million representing the Prior Term Loan End of Term Charge (the Prior Term Loan End of Term Charge and End of Term Charge, collectively the “End of Term Charges”).</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Term Loans mature on January 1, 2028, with no option for extension.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Term Loan bears cash interest payable monthly at an annual rate equal to the greater of (a) the prime rate of interest as reported in the Wall Street Journal plus <span style="font-size:10pt;font-~~

~~family:Times New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">0.75% (capped at 9.75%) and (b) 9.25%. The Term Loan also bears additional payment-in-kind interest at an annual rate of 1.15%, which is added to the outstanding principal balance of the Term Loan on each monthly interest payment date. Borrowings under the Amended Loan Agreement are repayable in monthly interest-only payments through the “Amortization Date”, which is either: (x) July 1, 2025 or (y) if the Interim Milestone is achieved and there has been no default, <span style="color:#000000;white-space:pre-wrap;font-~~

~~size:10pt;font-family:Times New Roman;min-width:fit-content;">January 1, 2026, or (z) if the Interim Milestone and certain clinical milestones are achieved and there has been no default, July 1, 2026. After the Amortization Date, the outstanding Term Loans and interest shall be repayable in equal monthly payments of principal and accrued interest until the Maturity Date. The effective interest rate of the Term Loan was 11.63% as of October 31, 2024. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">At the Company's option, the Company may elect to prepay all, but not less than all, of the outstanding Term Loan by paying the entire principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0<span~~

~~style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">% of the principal amount outstanding if the prepayment occurs in any of the first twelve months following the Closing Date; (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first twelve months following the Closing Date but on or prior to twenty-four months following the Closing Date; and (iii) 1.0% of the principal amount outstanding if prepayment occurs at any time thereafter but prior to the Maturity Date.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In connection with the Amended Loan Agreement, the Company granted Hercules a security interest senior to any current and future debts and to any security interest in all of the Company’s right, title, and interest in, to and under all of the Company’s property and other assets, subject to limited exceptions including the Company’s intellectual property.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Amended Loan Agreement contains~~

~~***negative covenants that, among other things and subject to certain exceptions, could restrict the Company's ability to incur additional liens, incur additional indebtedness, make investments, including acquisitions, engage in fundamental changes, sell or dispose of assets that constitute collateral, including certain intellectual property, pay dividends or make any distribution or payment on or redeem, retire or purchase any equity interests, amend, modify or waive certain material agreements or organizational documents and make payments of certain subordinated indebtedness. The Amended Loan Agreement also contains certain events of default and representations, warranties and non-financial covenants of the Company. The Company is in compliance with the financial covenants at October 31, 2024.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company accounted for the Amended Loan Agreement as an extinguishment of the Prior Term Loan. As a result of the extinguishment, the Company recorded a loss of $0.4 million as a component within other income and expense in the Company's consolidated statement of operations during the year ended October 31, 2024, which represented the difference between the reacquisition </p><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-***~~

~~***bottom:0;text-align:justify;">price of the debt, including fees and the initial fair value of the warrants paid directly to the lender, and the carrying value of the Prior Term Loan at the time of extinguishment.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">As of October 31, 2024, the Company had borrowed $22.5 million under the Amended Loan Agreement and incurred $2.2 million of debt discount and issuance costs inclusive of legal fees and End of Term Charges under the Term Loan.</p><p style="margin-left:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:6pt;text-align:justify;">First Amendment to Amended and Restated Loan and Security Agreement</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;"><span style="color:#000000;white-***~~

~~space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">On December 18, 2024, the Company entered into the First Amendment to Amended and Restated Loan and Security Agreement with Hercules, which amended the Amended Loan Agreement. See Note 19, Subsequent Events for additional information. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Hercules Common Share Warrants</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">In connection with the Amended Loan Agreement, the Company also agreed to issue to the Lenders in connection with each advance of Term Loans warrants to purchase that number of the Company's common shares, as shall be equal to 2% of the aggregate principal amount of such Term Loan advance divided by the Warrants per share exercise price of $7.21 (which exercise price equals the ten-day~~

~~volume weighted average price for the ten (10) trading days preceding the Hercules Closing Date and is subject to customary adjustments under the terms of the Warrants) (the “Hercules Common Share Warrants”). The Hercules Common Share Warrants are exercisable for a period of seven years from issuance.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Under the terms of the Amended Loan Agreement, the maximum number of Hercules Common Share Warrants and underlying Common Shares of the Company that could be issued is 138,696. On the Hercules Closing Date, the Company issued to the Lenders 62,413 Hercules Common Share Warrants in connection with the Tranche 1 Advance of the Term Loans (the “Closing Date Warrants”). The Closing Date Warrants have been~~

~~determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Company’s Common Shares as prescribed by ASC 815. Upon entering into the Amended Loan Agreement, $0.3 million of the total $22.5 million Tranche 1 Advance was allocated to the warrants, on a relative fair value basis, and recorded within additional paid in capital.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Subsequently issued Hercules Common Share Warrants shall be substantially in the form of the Closing Date Warrants. Under the terms of the Amended Loan Agreement, the maximum number of Hercules Common Share Warrants and resultant underlying common shares of the Company that could be issued is 138,696 (i.e. 2% of the $<span style="font-~~

~~***style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">0.7 million of the note payable as current, which represents the back-end fee associated with the refinancing of the Prior Term Loan. As of October 31, 2023, the Company classified $0.6 million of the note payable as current, which represents the principal payments due and amortization of the debt discount between October 31, 2023 and the date the Term Loan was amended in December 2023, as the debt was refinanced on a long-term basis in the subsequent event period. During the years ended October 31, 2024 and 2023, the Company recognized $2.2 million and $1.8<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-***~~

~~rates available to the Company for loans with similar terms and consideration of the Company’s credit risk, the carrying value of the Company’s variable interest rate debt, excluding unamortized debt issuance costs, approximates fair value.</p><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">April 2023 Notes</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On April 4, 2023, Old enGene entered into a note purchase agreement (the “April 2023 Notes”) for a principal amount of $8.0 million with Merck Lumira Biosciences Fund, L.P., Merck Lumira Biosciences Fund (Quebec), L.P., Lumira Ventures III, L.P., Lumira Ventures III (International), L.P., Lumira Ventures IV, L.P., Lumira Ventures IV (International), L.P., Fond de solidarité des travailleurs du Québec (F.T.Q.), and Forbion Capital Fund III Cooperatief U.A. (collectively the “April 2023 Investors”). The April 2023 Notes had an interest free period of 45 days from the date of issuance, and commencing on~~

~~the 46th day, began to accrue interest at a rate of 15% per annum. The April 2023 Notes were classified as current as they matured on the earlier of (i) July 31, 2023; or (ii) the date the Company completes a qualified financing, as defined within the April 2023 Notes as a financing pursuant to which the Company sells convertible promissory notes, warrants, preferred shares, common shares, or a combination thereof of the Company for an aggregate amount of at least $20.0 million. Upon the completion of the 2023 Financing (as defined below) in May 2023, Old enGene issued convertible debentures and warrants of Old enGene to the April 2023 Note investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing, as repayment of the April 2023 Notes.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company elected the fair value option of accounting for the April 2023 Notes. The Company recorded the April 2023 Notes at fair value upon the date of issuance, which was determined to be $8.0<span style="color:#000000;white-space:pre-wrap;font-~~

~~***style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;">September 29, 2025. The BDC Notes were convertible at the option of the holder into Old enGene's Class B redeemable convertible preferred shares at a price of 80% of the price paid per share in qualified financing, as defined within the BDC convertible debenture agreement. The issuance of the Prior Term Loan in 2021 met the definition of a qualified financing per the BDC convertible debenture agreement. As the conversion option was not exercised upon the issuance of the Prior Term Loan, the conversion rights upon a qualified financing were waived. There were optional conversion options that existed if Old enGene is in default, or in the event of certain liquidation events, as defined within the BDC Notes, which allow for conversion of the BDC Note into the most senior share outstanding at the time of the event. If a liquidation event, as defined within the BDC Note agreement, and which included a SPAC transaction, is consummated after a qualified financing, and optional conversion is not elected, the Company is required to pay the investor in cash, the outstanding principal and the accrued but unpaid interest and in addition an amount equal to 20% of the principal.<span style="color:#000000;white-space:pre-wrap;font-***~~

~~size:10pt;font-family:Times New Roman;min-width:fit-content;"> </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Upon issuance of the BDC Notes, the Company identified embedded derivatives related to the equity conversion features and liquidity event repayment features which required bifurcation as a single compound derivative instrument. The Company estimated the </p><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">fair value of the embedded derivative liabilities upon issuance at $0.2 million. The Company remeasured the fair value of the embedded derivatives in effect at each reporting period, with the subsequent changes in the fair value of the derivative being recognized in changes in fair value of derivatives within the Company's consolidated statements of operations and comprehensive loss. During the year ended October 31, 2023, the Company recorded a change in fair value of the convertible debentures~~

~~***embedded derivative liability associated with the BDC Note of $0.3 million. Total interest expense, including the amortization of debt discounts, of $0.3 million was recorded for the year ended October 31, 2023. Upon the close of the Reverse Recapitalization the Company repaid the BDC Note, including the liquidity event repayment amount, resulting in full settlement of the note and extinguishment of the embedded derivative liability. The estimated fair value of the embedded derivative liabilities at October 31, 2022 was $0.3 million, resulting in $0.3 million of expense recorded as change in fair value of convertible debentures embedded derivative liabilities in the consolidated statement of operations and comprehensive loss for the year ended October 31, 2022. Total interest expense, including the amortization of debt discounts, was $0.4<span***~~

~~***style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;"> million for the year ended October 31, 2022. As part of the issuance of the BDC Notes, the Company incurred an aggregate of $36 of debt issuance costs of which a portion were recorded as a reduction of the carrying value of the BDC Notes, and a portion was allocated to the embedded derivative liabilities which were expensed as incurred. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On May 12, 2023, the Company consented to certain modifications of the BDC Notes pursuant to which the Company will be required on the Closing Date to repay in cash (i) the outstanding principal and the accrued but unpaid interest; and (ii) an amount equal to 20% of the principal.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Upon the close of the Reverse Recapitalization, the Company repaid the BDC Note in full, resulting in a loss on extinguishment of $<span style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-***~~

~~width:fit-content;">9 thousand due to the difference between the repayment amount and the carrying amount of the debenture and fair value of the embedded derivative lability at the time of repayment. </p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">2022 Notes</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">During the year ended October 31, 2022, Old enGene issued convertible debentures for an aggregate amount of $18.4 million on October 20, 2022 (the “2022 Notes”). The 2022 Notes had an initial maturity that is the later of (i) three years from the date of issuance; or (ii) the maturity date of the Prior Term Loan. See Note 8, License Agreement and Clinical Research Organization. The 2022~~

~~***Notes bear interest at 10% per annum commencing on the date of issuance. The 2022 Notes are automatically convertible into common shares or redeemable convertible preferred shares of Old enGene upon certain events. Upon the close of the Reverse Recapitalization, the 2022 Notes were converted into 2,081,359 Common Shares of the Company.</p> <p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Upon issuance of the 2022 Notes, the Company identified embedded derivatives related to the equity conversion features which required bifurcation as a single compound derivative instrument. The Company estimated the fair value of the embedded derivative liabilities upon issuance at $3.5 million. Given the close proximity between the issuance date of the notes and the Company’s year ended October 31, 2022, no change in fair value was recorded related to the embedded derivative liabilities identified as part of the issuance of the 2022 Notes. During the year ended October 31, 2023, the Company recorded a change in fair value associated with the 2022 Notes ***~~

~~***embedded derivative liability of $21.2 million in the consolidated statement of operations and comprehensive loss for the year ended October 31, 2023. As of October 31, 2023 no embedded derivative liability is recorded for the 2022 Notes as they converted to shares of the Company upon the consummation of the Reverse Recapitalization. Total interest expense, including the amortization of debt discounts, was $2.8 million for the year ended October 31, 2023, respectively. As part of the issuance of the 2022 Notes, the Company incurred an aggregate of $44 thousand of debt issuance costs of which a portion were recorded as a reduction of the carrying value of the 2022 Notes, and a portion was allocated to the embedded derivative liabilities which were expensed as***~~

~~incurred.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On May 16, 2023, the Company agreed to certain modifications of the 2022 Notes having an aggregate principal amount of $18.4 million (the “Amended 2022 Financing”), which included a change in the definition of the maturity date by allowing an extension of the maturity date upon election of a noteholder majority, increasing the percentage required for a noteholder majority, and modifying terms of certain conversion options. The amendments to the 2022 Notes did not result in the addition or termination of any substantive conversion terms, and the amendment to the 2022 Notes was determined to be non-substantial and was accounted for as a modification. In addition, as part of the May 2023 Financing, the holders of the 2022 Notes which participated in the 2023 Financing received warrants to purchase common shares of the Company. The fair value of the warrants at the time of issuance to the holders of the 2022 Notes was determined to be $0.5<span style="color:#231f20;white-~~

~~space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;"> million and was recorded as reduction of the carrying value of the 2022 Notes as part of the modification, which is being amortized to interest expense through the maturity date of the 2022 Notes.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On October 31, 2023 upon the close of the Reverse Recapitalization, the 2022 Notes were converted into 2,081,359 Common Shares of the Company. The Company accounted for the conversion as an extinguishment and recorded a loss on extinguishment of </p><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">$3.1 million, relating to the difference between the fair value of the common shares issued and the carrying value of the 2022 Notes and fair value of the embedded derivative liability at the time of conversion.~~

~~ </p><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">May 2023 Notes </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On May 16, 2023, concurrently with the execution and delivery of the Merger Agreement, Old enGene entered into agreements pursuant to which it agreed to issue new convertible notes and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in repayment of the April 2023 Notes in an aggregate amount of $8.0 million (collectively, the “May 2023 Notes” and, together with the warrants purchased concurrently, the “2023 Financing”; the 2023 Financing together with the Amended 2022 Financing, the “Convertible Bridge Financing”).<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New~~

~~Roman;min-width:fit-content;"> </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The 2023 Financing occurred in two separate issuances with $28.0 million issued in May 2023 for $20.0 million in cash and $8.0 million in repayment of the April 2023 Notes, and an additional $10.0 million issued in June 2023 for $10.0 million in cash, of which Forbion Growth Sponsor FEAC I B.V. funded an aggregate amount of~~

~~$20.0 million of the total $38.0 million. The May 2023 Notes issued as part of the 2023 Financing, if not converted, have an initial maturity date of October 20, 2025 and are to accrue interest at 10% per annum, which is payable upon maturity. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The warrants issued as part of the 2023 Financing were for the purchase of common shares of Old enGene. The 2023 Warrants were only to become exercisable upon the completion of the merger. Upon the close of the Reverse Recapitalization,~~

~~***the 2023 Warrants were exchanged for 2,679,432 warrants of the Company and have the same terms as the public warrants issued upon the FEAC initial public offering, with an exercise price of $11.50, and which will expire five years after the completion of the merger.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The warrants issued as part of the 2023 Financing were concluded to be liability classified upon issuance, as they failed the fixed for fixed criteria that is required for a contract to be considered indexed to the Company’s own stock as prescribed by ASC 815. The terms of the warrants initially required the Company to issue a variable number of shares until the PIPE Financing was executed, at which time the number of warrants became fixed. The 2023 Warrants were initially and subsequently measured at fair value with any changes in fair value recorded as a component of other income and expense within the change in fair value of warrant liabilities. See Note 3, Reverse Recapitalization. Upon the execution of the PIPE Financing and consummation of the Reverse Recapitalization, the warrants were reclassified to equity as the number of warrants became fixed and it was determined that the warrants met the fixed for fixed criteria that is required for a contract to be considered indexed to the Company’s***~~

~~own stock as prescribed by ASC 815.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company elected the fair value option of accounting for the May 2023 Notes. The Company recorded May 2023 Notes at fair value upon the date of issuance. At inception the fair value of the May 2023 Notes was determined to be $37.0 million and the fair value of the related warrants was determined to be $1.4 million, of which $0.5 million related to the fair value of the warrants issued to the holders of the 2022 Notes, as described above. During the year ended October 31, 2023, the Company recorded a change in fair value of the May 2023 Notes of $56.2 million. The Company incurred $~~

~~***0.8 million of debt issuance costs associated with the May 2023 Notes which have been expensed and are included within general and administrative expenses. See Note 3, Reverse Recapitalization.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On October 31, 2023 upon the close of the Reverse Recapitalization, the 2023 Notes were converted into 4,298,463 common shares of the Company. The Company accounted for the conversion as an extinguishment, with no gain or loss recorded on extinguishment as the fair value of the common shares issued was determined to equal the fair value of the 2023 Notes at the time of conversion.</p>0022000000.082023-09-282025-09-290.800.2020000003000000300000030000003000000400000036***~~

~~***10-200.10267943211.537000000014000000500000056200000080***~~

~~***style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">11. Redeemable Convertible Preferred Shares</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-***~~

~~align:justify;">As of October 31, 2022, Old enGene’s Articles of Amendment had an unlimited number of authorized shares of each class of redeemable convertible preferred shares. </p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Class A Redeemable Convertible Preferred Shares</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On July 26, 2013, the Company entered into a subscription agreement (the “Class A Agreement”) with multiple investors, whereby the Company agreed to sell to the investors an initial aggregate amount of 610,333 Class A redeemable convertible preferred shares at a price of $1.5929 ($1.63845<span~~

~~***style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;"> CAD) per share for total aggregate proceeds of $1.0 million (the “Class A Initial Closing”). Included within the Class A Agreement were three additional future tranche obligations (the “Class A Second Tranche,” “Class A Third Tranche” and “Class A Fourth Tranche”) for the Company to issue and sell shares of Class A redeemable convertible preferred shares upon the achievement of certain milestone events. Only the Class A Second Tranche closed under the Class A Agreement. The Class A Second Tranche obligated the Company to sell and the Class A Investors to purchase 1,830,999 shares of Class A redeemable convertible preferred shares at a price of $1.56967 ($1.63845 CAD) per share for total proceeds of $ 2.9<span***~~

~~***style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;"> million, upon the establishment of the </p><p style="font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Company’s headquarters in Montreal Quebec and completion of experiments required to bolster a patent application for dually-derivatized chitosan (the “Second Closing Milestone Event”), which occurred in 2013. Additionally, upon completing the Class A redeemable convertible preferred share financing, convertible notes of the Company held by multiple investors converted into Class A redeemable convertible preferred shares. </p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Class B Redeemable Convertible Preferred Shares</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On January 6, 2015, the Company entered into a subscription agreement (the***~~

~~“Class B Agreement”) with multiple investors, where the Company agreed to sell to the investors an initial aggregate amount of 2,758,221 Class B redeemable convertible preferred shares at a price of $1.85032 ($2.17532 CAD) per share for total proceeds of $ 5.1 million (the “Class B Initial Closing”). Included within the Class B Agreement were two additional closings (the “Class B Second Tranche,” and the “Class B Third Tranche,” respectively) which obligated the Company to sell and Class B investors to purchase additional Class B redeemable convertible preferred shares upon certain events. The Class B Second Tranche obligated the Company to sell and the Class B Investors to purchase 1,838,815<span style="color:#000000;white-space:pre-wrap;font-~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;"> Class B Shares at a price of $1.63419 ($2.17532 CAD) per share for total proceeds of $3.0 million and the Class B Third Tranche obligated the Company the sell and the Class B Investors to purchase 1,608,963 Class B Shares at a price of $1.63419 ($2.17532 CAD) per share for total proceeds of $<span style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-***~~

~~***width:fit-content;">2.6 million. The Class B Second Tranche and Class B Third Tranche closed on March 1, 2017.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Class B-1 Redeemable Convertible Preferred Shares</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On September 10, 2015, the Company entered into a Subscription Agreement (the Class “B-1 Agreement”), in which the Company was to issue 1,523,809 Class B-1 redeemable convertible preferred shares for a purchase price of $1.64367 ($2.17532 CAD) per share, resulting in aggregate proceeds of $2.5<span***~~

~~style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;"> million. During the year ended October 31, 2020, the Class B-1 redeemable convertible preferred shares converted to common shares on a 1:1 basis. Therefore, as of each of the years ended October 31, 2023, October 31, 2022, and October 31, 2021, no shares of the Class B-1 redeemable convertible preferred shares remained outstanding. The Company presented these shares within temporary equity, as they contained the same redemption features as the Class B redeemable convertible preferred shares (further described above). Upon conversion to common shares, the carrying value of the Class B-1 redeemable convertible preferred shares was reclassified to additional paid in capital within shareholders' deficit.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Class C Redeemable Convertible Preferred Shares</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Class C redeemable convertible preferred shares are issuable in series, of which an unlimited number are designated as Series 1 Class C redeemable convertible preferred shares with an issue price per share of $1.5929<span~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;">10 years. The Class C Warrants were determined to be liabilities. The Company estimated the fair value of the warrant liabilities upon issuance and remeasured the fair value of the warrant liabilities at each reporting period, with the subsequent changes in the fair value of the warrant liabilities being recognized in changes in fair value of warrant liabilities within the Company's consolidated statements of operations and comprehensive loss. Upon the completion of the merger with FEAC, all existing Class C Warrants of the Company will be extinguished. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Under the terms of the Class C Agreement, certain convertible notes held by various Class C investors and other investors were exchanged for an aggregate amount of 16,464,646 Class B redeemable convertible preferred shares. Additionally, upon entering into the Class C Agreement, the Company also entered into a share exchange agreement (the "Share Exchange Agreement") with the Class A investors and the Class B investors. As part of the Share Exchange Agreement, certain of the Class A redeemable convertible preferred shares issued to Class A investors were exchanged for Series 1 Class C redeemable convertible preferred shares and certain of***~~

~~the Class B redeemable convertible preferred shares issued to the Class B investors were exchanged for Series 2 Class C redeemable convertible preferred shares. This exchange resulted in the derecognition of Class A and B redeemable convertible preferred shares and the recognition of Class C redeemable convertible preferred shares at the fair value of the Class C redeemable convertible preferred shares. The difference between the carrying value of the Class A and Class B redeemable convertible preferred shares and the fair value of the Class C redeemable convertible preferred shares for which they converted into was recorded within additional paid in capital and no gain or loss on extinguishment was recorded within the consolidated statements of operations and comprehensive loss. Further, the February 2020 Warrants, June 2020 Warrants, and 2021 Warrants, which consisted of warrants to purchase the Company's Class B redeemable convertible preferred shares and were issued as part of the convertible debentures were cancelled and replaced by the terms of the Class C Warrants. The aggregate amount of outstanding warrants of 10,242,130 from the February 2020 Warrants, the June 2020 Warrants, and the 2021 Warrants converted into 10,242,130 Class C Warrants, which have an exercise price of $2.12376<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-~~

~~***content;"> ($2.6320 CAD) per share and a term expiring on February 14, 2030. Immediately prior to conversion, the warrants were marked to fair value, with the change in the fair value of the warrant liabilities being recognized in changes in fair value of warrant liabilities within the Company’s consolidated statements of operations and comprehensive loss. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Upon issuance of each series of Class A, Class B, and Class C Preferred Shares, the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features. </p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Conversion of***~~

~~***Redeemable Convertible Preferred Stock</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Pursuant to the terms of the Merger Agreement, upon the consummation of the Reverse Recapitalization, each share of Old enGene’s redeemable convertible preferred stock issued and outstanding immediately prior to the close was exchanged for common shares of the Company using the Company Exchange Ratio of approximately 0.18048. A retrospective adjustment has been applied to all periods presented to reflect the Reverse Recapitalization. See Note 3, Reverse Recapitalization for additional discussion.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Undesignated Preferred Stock</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company’s Certificate of Incorporation, as amended and restated, authorizes the Company to issue an unlimited number of preferred shares with no par value. The shares of preferred stock are currently undesignated.</p>6103331.59291.638451000000018309991.569671.6384***~~
~~***02-140.18048<p style="font-size:10pt;margin-***~~

~~width:fit-content;">aling $6.0 million.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The number of Common Shares to be issued upon the cashless exercise is equal to the quotient obtained by dividing (x) the product of the number of shares underlying the warrants, multiplied by the excess of the “Fair Market Value” over the warrant exercise price of $11.50 by (y) the Fair Market Value. The Fair Market Value is the volume weighted average price of the shares for the ten (10) trading day period ending on the trading day prior to the date that notice of exercise is received by the Company’s Warrant Agent from the holder or its broker or intermediary. The warrants had a cashless exercise period until such time as the registration statement under the Securities Act with respect to the enGene Common Shares underlying the enGene Warrants was declared effective, which occurred on March 5, 2024. The Company may elect to call in the warrants for redemption if the share price of the Company equals or exceeds $<span style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-~~

~~wrap;min-width:fit-content;">18.00 for any twenty (20) trading days within the thirty (30) trading-day period ending on the third (3rd) trading day prior to the date on which notice of the redemption is given, subject to adjustments as provided in the terms of the warrant agreement.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The common share warrants have been determined to be equity classified as they do not meet the definition of a liability under ASC 480 and are considered indexed to the Company’s common shares as prescribed by ASC 815.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">As described in Note 9, Notes Payable, the additional 62,413 of the warrants to purchase Common Shares outstanding as of October 31, 2024, were issued as part of the Amended Term Loan on December 22, 2023, have an exercise price of<span style="color:#231f20;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-~~

~~bottom:0;text-align:left;"> </p></td> </tr> </table>85119681041164160345122706941275288926079~~

~~style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;">13. Share-Based Compensation </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Pursuant to the terms of the Reverse Recapitalization, upon the Closing Date, each outstanding option to purchase Old enGene's common stock issued under the Old Plan's was exchanged for an option to purchase common shares of the Company, and the number of shares and exercise price of each granted option was adjusted using the exchange ratio of approximately 0.18048. Further, the currency of all exercise prices of the options issued under the Old Plans were converted from CAD to USD using the exchange rate in effect on the day immediately prior to the Closing Date. A retrospective adjustment has been applied to the number of options and exercise price of stock options for all periods presented to reflect the Reverse Recapitalization as discussed further in Note 3.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;"><span style="color:#000000;white-space:pre-wrap;font-~~

~~size:10pt;font-family:Times New Roman;font-style:italic;min-width:fit-content;">The Old Plans </p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Old enGene had an employee share option plan (the “ESOP”) and an equity incentive plan (the “EIP”) (collectively, the “ Old Plans”) which was adopted by the Board of Directors, and approved by the shareholders, effective July 5, 2018.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Under the Old Plans, options to purchase non-voting common shares of Old enGene’s shares may be granted to directors, officers, employees, consultants and members of the scientific advisory board. The Old Plans provide for the issuance of common stock options up to a maximum of 15% of the aggregate issued and outstanding common shares and non-voting common shares of Old enGene calculated on an as converted and fully diluted basis. The Old Plans were administered by Old enGene’s Board of Directors. Old enGene’s Board of Directors determined the number of options to be granted, the vesting period and the exercise price of new options. It was Old enGene’s policy to establish the exercise price at an amount that approximates the fair value of the~~

~~***underlying shares on the date of grant as determined by Old enGene’s Board of Directors. The options vest in accordance with the vesting terms determined for each grant by Old enGene’s Board of Directors. The vesting terms of Old enGene’s granted stock options with service only conditions are typically 100% vesting immediately upon grant date, or over a three- or four-year service period. Upon the consummation of the Reverse Recapitalization, the Company recognized share-based compensation expense of $0.4 million associated with the acceleration of the vesting for the outstanding awards with service only vesting conditions under the Old Plan. As of October 31, 2024 and 2023, <span style="font-size:10pt;font-***~~

~~family:Times New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">no unrecognized compensation cost remains for the outstanding awards granted under the Old Plan with service only vesting conditions. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On July 7, 2023, the Board of Directors approved the reservation of an additional 1,046,764 non-voting common shares for issuance under the Company’s employee equity incentive plan, revising the number of shares reserved from 1,775,729 to 2,822,493. Also on July 7, 2023, the Company granted 1,046,764<span style="color:#000000;white-space:pre-wrap;font-~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;"> options to employees at an exercise price of $5.87 CAD ($4.24 USD). These options are not exercisable unless and until the completion of the Reverse Recapitalization and there is an effective registration statement for the shares underlying such granted options and will terminate automatically in the event of the termination of the Merger Agreement. The Company has valued these awards at the grant date using Black-Scholes pricing model in which the fair value of the stock on the grant date was equal to the exercise price of the award. The expected term has been determined using management’s best estimate considering the characteristics of the award, contractual life, the timing of the expected achievement of the performance conditions, the remaining time-based vesting period, if any, and comparison to expected terms used by peers. Upon the grant date, 794,643 of the issued options were fully vested, and the remaining 252,121<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-***~~

~~content;"> options will vest over varying terms up to four years on a pro rata basis. The Company recognizes compensation expense when achievement of the performance condition is deemed probable using an accelerated attribution method, as if each vesting tranche was treated as an individual award. During the year ended October 31, 2023, $2.6 million of stock based compensation expense was recorded associated with the 1,046,764 stock options granted in July 2023 because the Reverse Recapitalization was completed and the Company determined that the filing of the registration statement was probable to occur. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Upon the consummation~~

~~of the Reverse Recapitalization on October 31, 2023, all options outstanding under the Old Plans were exchanged for 2,706,941 shares options to purchase common shares of the Company based on the Exchange Ratio determined in accordance with the terms of the Merger Agreement. Further, all exercise prices were adjusted by the Exchange Ratio and the currency of the exercise prices was changed from CAD to USD based on the exchange rate in effect on October 30, 2023, the day immediately before the consummation of the Reverse Recapitalization. No incremental compensation cost was recorded as a result of the change in underlying common shares from Old enGene to the Company, or as a result of the change of the exercise prices to reflect the adjustment for the Exchange Ratio and the change in currency from CAD to USD, as it was concluded that the fair value of the awards immediately before and immediately after the modifications did not change. No options remain available for grant under the Old Plans as of October 31, 2023.</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;"><span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;font-~~

~~***style:italic;min-width:fit-content;">The 2023 Plan</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On October 31, 2023, upon the completion of the Reverse Recapitalization, the shareholders approved and the Company adopted the enGene Holdings Inc. 2023 Incentive Equity Plan (the “2023 Plan”), which superseded the Old Plans. The 2023 Plan authorizes the award of incentive stock options, or ISOs, non-qualified stock options, or NQSOs, Stock Units, Stock Appreciation Rights, or SARs, and other share-based awards including performance awards and share bonus awards.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The number of shares initially reserved for issuance under the 2023 Plan is 2,607,943 Common Shares, plus 2,706,941 common shares subject to the outstanding grants under the Old Plans, and shall automatically increase on January 1 of each calendar year beginning in 2024 by a number of shares equal to the lesser of <span style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-***~~

~~***width:fit-content;">1,946,226 Common Shares and such lesser number as may be determined by the Board. The Common Shares authorized under the 2023 Plan increased by 1,946,226 on January 2, 2024. As of October 31, 2024, the total number of Common Shares reserved for issuance under the 2023 Plan is 7,261,110, and there are 2,752,889 shares remaining for issuance.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The 2023 Plan is administered by the Board or, at the discretion of the Board, by a committee of the Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than <span style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-width:***~~

~~***width:fit-content;">100% of the fair market value of the Common Shares on the date of grant and the </p><p style="font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">term of stock option may not be greater than ten years. Common Shares that are expired terminated, surrendered or cancelled under the 2023 Plan without having been fully exercised will be available for future awards.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On May 15, 2024, the shareholders of the Company approved changes to the 2023 Plan. The original 2023 Plan contained an evergreen provision (the “Evergreen Provision”) pursuant to which, commencing with the first business day of each calendar year beginning in 2024, the aggregate number of the Company’s Common Shares that could be issued or***~~

~~transferred thereunder (the “Plan Share Reserve”) and the number of Common Shares available for options intended to qualify as incentive stock options (the “ISO Sublimit”) each increased by a number of Common Shares equal to the lesser of (x) 1,946,226 Common Shares and (y) such lesser number of Common Shares as may be determined by the Compensation Committee. Pursuant to the Amended and Restated enGene Holdings Inc. 2023 Incentive Equity Plan, on May 15, 2024, the Evergreen Provision was amended to provide for annual increases on the first business day of each calendar year of (i) the Plan Share Reserve by such number of Common Shares as equals 5% of the aggregate number of Common Shares outstanding on the final day of the immediately preceding calendar year (or such smaller number of shares as is determined by the compensation committee), and (ii) the ISO Sublimit by the lesser of 2,500,000 Common Shares and the increase in the Plan Share Reserve (or such smaller number of shares may be determined by the compensation committee of the Company’s board of directors).</p><p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:left;"><span~~

~~break:keep-all;display:inline-flex;justify-content:flex-start;">(iv)<div style="width:100%;display:inline;">extension of the period to exercise his vested equity awards to three years following the later of date of termination of his employment or the date of termination of the Consulting Period (as defined below), but in no event shall the post-termination exercise period of the CEO’s vested equity awards extend beyond the respective applicable term thereof.</div></div><p style="text-indent:6.667%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:12pt;text-align:justify;">The Transition Agreement further provided that, in the e2,vent Mr. Hanson were to resign upon the appointment by the Company of a new chief executive officer, Mr. Hanson would be immediately engaged in a consulting role to provide transition services as a Senior Strategic Advisor to the Company for a period of at least six months following the effective date of resignation (the “Consulting Period”) in exchange for a monthly fee of $25,000 for the initial six-month Consulting Period, and $<span style="font-size:10pt;font-family:Times New~~

~~***Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">500 per hour thereafter, provided that Mr. Hanson need not devote more than fifteen (15) hours per week to providing such transition services.</p><p style="text-indent:6.667%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Under the Transition Agreement, the 1,216,266 stock option awards issued to Mr. Hanson were modified to allow for an extended exercise period as described above. The modification resulted in an incremental share-based compensation expense of $1.0 million which was recorded upon the effective date of the Transition Agreement. </p><p style="text-indent:6.667%;font-size:10pt;margin-top:6pt;font-***~~

~~family:Times New Roman;margin-bottom:0;text-align:justify;">Mr. Hanson resigned effective as of July 19, 2024 in connection with the Company’s appointment of a new chief executive officer. On July 20, 2024, enGene appointed Ronald H. W. Cooper as Chief Executive Officer of the Company and as director of the Company's Board of Directors.</p><p style="text-indent:6.667%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Additionally, in 2024, the Company entered into a Severance Agreement with each of three former employees, including the former Chief Medical Officer and the former Chief Scientific Officer. Under the terms of Severance Agreement, the employees are entitled to twelve months of continued pay and health insurance benefits; a payment of a 2024 target annual bonus prorated through the last day of employment, acceleration and vesting of any then unvested time-based equity awards that would have vested in the twelve-month period following such termination and an extended expiry period, which resulted in a stock-based compensation modification. Under the terms of the agreements, 231,684 stock <span~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;">The Company records uncertain tax positions as liabilities in accordance with ASC 740 and adjusts these liabilities when the Company’s judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of October 31, 2024 and 2023, no uncertain tax positions have been recorded in the consolidated financial statements.</p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations and comprehensive loss. As of October 31, 2024 and 2023, no<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-***~~

~~top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">Purchase and Other Obligations </p>The Company enters into contracts in the normal course of business with CROs, CDMOs and other third-party vendors for nonclinical research studies and testing, clinical trials and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including those incurred by subcontractors of our suppliers.<p style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">18. Related Party Transactions</p><p style="text-indent:4.533%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">During the year ended October 31, 2024 and 2023, the Company had the following transactions with shareholders that hold more than <span style="font-size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-~~

~~width:fit-content;">10% of the total outstanding shares of the Company:</p><p style="text-indent:4%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:6pt;text-align:justify;">On February 20, 2024, the Company completed the February 2024 PIPE Financing, which provided for the private placement of 20,000,000 Common Shares, at a price of $10.00 per share and included both new and existing investors. One of the Company’s directors, Mr. Gerald Brunk, is a managing director of Lumira Ventures (“Lumira”), and certain entities affiliated with Lumira were party to the 2024 Subscription Agreements, purchasing an aggregate of 800,000 Common Shares for a total price of $8.0<span style="color:#000000;white-space:pre-wrap;font-~~

~~***size:10pt;font-family:Times New Roman;min-width:fit-content;"> million in the February 2024 PIPE Financing. </p><p style="text-indent:4%;font-size:10pt;margin-top:6pt;font-family:Times New Roman;margin-bottom:6pt;text-align:justify;">On October 29, 2024, the Company completed the October 2024 PIPE Financing, which provided for the private placement of 6,758,311 Common Shares at a price of $8.90 per share and included both new and existing investors. Two of the Company’s directors, Messrs. Jasper Bos and Wouter Joustra, are general partners of FEAC, and an entity affiliated with FEAC was party to one of the October 2024 Subscription Agreements, purchasing an aggregate of 561,797 Common Shares for a total price of approximately $5.0<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-***~~

~~content;"> million in the October 2024 PIPE Financing. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On April 4, 2023, the Company entered into the April 2023 Notes for a principal amount of $8.0 million with the April 2023 investors, as described in Note 8. The April 2023 Notes had an interest free period of 45 days from the date of issuance, and commencing on the 46th day, is to accrue interest at a rate of 15% per annum. The April 2023 Notes had a maturity date which was the earlier of (i) July 31, 2023; or (ii) the date the Company completes a qualified financing, as defined within the April 2023 Notes as a financing pursuant to which the Company sells convertible promissory notes, warrants, preferred shares,~~

~~common shares, or a combination thereof of the Company for an aggregate amount of at least $20.0 million. Upon the completion of the 2023 Financing, which met the definition of a qualified financing as defined within the April 2023 Notes, the Company issued and aggregate amount of $8.0 million of convertible debentures and warrants of the Company to the April 2023 Note investors, on the same terms and conditions of the convertible debentures and warrants that were issued to the investors of the 2023 Financing, for the extinguishment and settlement of the April 2023 Notes. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On May 16, 2023, concurrently with the execution and delivery of the Merger Agreement, the Company entered into agreements pursuant to which it issued new convertible indebtedness and warrants (i) for cash in an aggregate principal amount of $30.0 million and (ii) in settlement and~~

~~extinguishment of the April 2023 Notes for an aggregate amount of $8.0 million, as described in Note 9, Notes Payable. The 2023 Financing occurred in two separate issuances with $28.0 million issued in May 2023 for $20.0 million in cash and $8.0 million in repayment of the April 2023 Notes, and an additional $10.0 million issued in June 2023 for $10.0 million in cash. The 2023 Notes issued as part~~

~~of the 2023 Financing have an initial maturity date of three years from the closing date and are to accrue interest at 10% per annum, which is payable upon maturity. The 2023 Notes have the same conversion terms as the 2022 Notes (as described in Note 9, Notes Payable). Of the $38.0 million of convertible debentures and warrants issued, $8.0 million was issued to existing shareholders of the Company, $20.0 million was issued to Forbion Growth Sponsor FEAC I B.V., and $10<span~~

~~***style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-content;"> million which was issued to Investissement Québec. </p><p style="text-indent:4.533%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On October 31, 2023, upon the consummation of the Reverse Recapitalization, all of the Old enGene's redeemable convertible preferred shares outstanding immediately prior to the close were exchanged for shares of the Company's common shares, with no dividends or distributions being declared or paid on Old enGene's redeemable convertible preferred shares. Further, certain of Old enGene's existing convertible notes were converted into common shares of Old enGene at the conversion ratio in place at the time of conversion, and all of Old enGene's common shares were exchanged for common shares of Company at the Exchange Ratio of approximately 0.18048. A total of <span style="font-***~~

~~size:10pt;font-family:Times New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">13,091,608 common shares of the Company were issued to the Old enGene's equity and convertible note holders upon the close of the Reverse Recapitalization, of which 2,262,351 were issued to Forbion Growth Sponsor FEAC I B.V, as a result of its' participation in the 2023 Financing. Each of Old enGene's outstanding warrants to purchase common shares were exchanged for 2,679,432 common share warrants upon the close of the Reverse Recapitalization of which 950,153 were issued to Forbion Growth Sponsor FEAC I B.V, as a result of its' participation in the 2023 Financing. All of Old enGene's existing outstanding Class C Warrants outstanding at the time of the Reverse Recapitalization were terminated. Additionally, there were 3,670,927<span style="color:#000000;white-space:pre-wrap;font-size:10pt;font-family:Times New Roman;min-width:fit-~~

~~content;"> common shares of the Company issued to FEAC and its shareholders, as part of the Reverse Recapitalization, along with 5,029,444 warrants to purchase common shares. </p>0.100.102000000010800000800000067583118.95617~~

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~~style="font-size:10pt;margin-top:18pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">19. Subsequent Events</p><p style="text-indent:4%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">On December 18, 2024 the Company entered into the First Amendment to Amended and Restated Loan and Security Agreement with Hercules (the “First Amendment”), which amended the Amended Loan Agreement dated December 22, 2023. Pursuant to the First Amendment, the $7.5 million advance originally available upon achievement of the Interim Milestone (defined above) was added to the uncommitted tranche subject to the Lenders’ investment committee approval and satisfaction of certain other conditions precedent (including payment of a <span style="font-size:10pt;font-family:Times~~

~~New Roman;color:#000000;white-space:pre-wrap;min-width:fit-content;">0.75% facility charge on the amount borrowed), pursuant to which the Company may request from time to time that the Lenders make additional term loan advances to the Company in an aggregate principal amount of up to $27.5 million. The Amended Term Loan Agreement did not change the total term loan facility available to the Company of up to $50.0 million. </p><p style="text-indent:4%;font-size:10pt;margin-top:12pt;font-family:Times New Roman;margin-bottom:0;text-align:justify;">The Company has evaluated subsequent events through the date these financial statements were issued. The Company concluded that no additional subsequent events have occurred that require disclosure.</p>75000000.0075275000000050000000 (1) The presentation of accrued financing costs as of October 31, 2023 has been updated to conform with presentation as of October 31, 2024.~~

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