OUTLOOK THERAPEUTICS, INC._September 30, 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of Contentsâ€‹â€‹UNITED STATESSECURITIES AND EXCHANGE COMMISSIONWASHINGTON, D.C. 20549FORMÂ 10-Kâ€‹â€‹â€‹â˜’ANNUAL REPORT PURSUANT TO SECTIONÂ 13 OR 15(d)Â OF THE SECURITIES EXCHANGE ACT OF 1934â€‹For the fiscalÂ year ended September 30, 2024ORâ€‹â€‹â˜TRANSITION REPORT PURSUANT TO SECTIONÂ 13 OR 15(d)Â OF THE SECURITIES EXCHANGE ACT OF 1934â€‹For the transition period fromÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â toÂ Commission File Number: 001-37759OUTLOOK THERAPEUTICS, INC.(Exact name of registrant as specified in its charter)â€‹â€‹â€‹DelawareÂ Â Â Â 38-3982704(State or other jurisdiction of incorporation or organization)â€‹(I.R.S. Employer Identification No.)â€‹â€‹â€‹â€‹111 S. Wood Avenue, Unit #100â€‹â€‹Iselin, New Jerseyâ€‹08852(Address of principal executive offices)â€‹(Zip Code)â€‹(609) 619-3990(Registrantâ€™s telephone number, including area code)Securities registered pursuant to SectionÂ 12(b)Â of the Act:â€‹â€‹â€‹â€‹â€‹â€‹Title of each classÂ Â Â Â Trading Symbol(s)Â Â Â Â Name of each exchange on which registeredCommon Stockâ€‹OTLKâ€‹The Nasdaq Stock Market LLCâ€‹â€‹â€‹â€‹â€‹Securities Registered Pursuant to SectionÂ 12(g)Â of the Act: NoneIndicate by check mark if the registrant is a well-known seasoned issuer, as defined in RuleÂ 405 of the Securities Act. Yes â˜ No â˜’Indicate by check mark if the registrant is not required to file reports pursuant to SectionÂ 13 or SectionÂ 15(d)Â of the Act. Yes â˜ No â˜’Indicate by check mark whether the registrant (1)Â has filed all reports required to be filed by SectionÂ 13 or 15(d)Â of the Securities Exchange Act of 1934 during the preceding 12Â months (or for such shorter period than the registrant was required to file such reports), and (2)Â has been subject to such filing requirements for the past 90Â days.Â YesÂ â˜’Â NoÂ â˜Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to RuleÂ 405 of Regulation S-T (Â§ 232.405 of this chapter) during the preceding 12Â 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 definition of â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmaller reporting company,â€ and â€œemerging growth companyâ€ in RuleÂ 12b-2 of the Exchange Act.â€‹â€‹â€‹â€‹Large accelerated filer â˜Accelerated filer â˜Non-accelerated filer â˜’Smaller reporting company â˜’â€‹â€‹Emerging growth company 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 SectionÂ 13(a)Â 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 registrant is a shell company (as defined in RuleÂ 12b-2 of the Exchange Act). Yes â˜ No â˜’The aggregate market value of the registrantâ€™s common stock, held by non-affiliates of the registrant as of MarchÂ 31, 2024 (which is the last business day of registrantâ€™s most recently completed second fiscal quarter) based upon the closing market price of such stock on The Nasdaq Capital Market on that date, was approximately $180.4 million.As of December 24, 2024, the registrant had outstanding 24,905,635 shares of common stock, par value $0.01 per share.DOCUMENTS INCORPORATED BY REFERENCEPart III of this report incorporates information by reference from the Company's definitive proxy statement, which proxy statement is due to be filed with the Securities and Exchange Commission not later than 120 days after September 30, 2024.â€‹â€‹â€‹Table of ContentsOUTLOOK THERAPEUTICS, INC.ANNUAL REPORT ON FORM 10-KTABLE OF CONTENTSâ€‹â€‹â€‹â€‹â€‹Pageâ€‹â€‹In this report, unless otherwise stated or as the context otherwise requires, references to â€œOutlook Therapeutics,â€ â€œOutlook,â€ â€œthe Company,â€ â€œwe,â€ â€œus,â€ â€œourâ€ and similar references refer to Outlook Therapeutics, Inc. (formerly known as Oncobiologics, Inc.) and its consolidated subsidiaries. The Outlook logo, Oncobiologics logo, LYTENAVA and other trademarks or service marks of Outlook Therapeutics, Inc. appearing in this report are the property of Outlook Therapeutics, Inc. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.Currency translations between Swiss Francs, or CHF, and U.S. dollars provided herein are based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York on September 30, 2024, or CHF 0.9015 = $1.00. We do not represent that CHF were, could have been, or could be, converted into U.S. dollars at such rate or at any other rate.â€‹â€‹â€‹Table of ContentsCAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATAThis Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are based on our managementâ€™s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical fact are â€œforward-looking statementsâ€ for purposes of these provisions, including those relating to future events or our future financial performance and financial guidance. In some cases, you can identify forward-looking statements by terminology such as â€œanticipate,â€ â€œbelieve,â€ â€œcontinue,â€ â€œestimate,â€ â€œexpect,â€ â€œintend,â€ â€œmay,â€ â€œmight,â€ â€œplan,â€ â€œproject,â€ â€œpredict,â€ â€œpotential,â€ â€œshould,â€ â€œwill,â€ the negative of terms like these or other comparable terminology, in connection with any discussion of future operating or financial performance. These statements are only predictions. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Any or all of our forward-looking statements in this document may turn out to be wrong. Actual events or results may differ materially. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks, uncertainties and other factors. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail in Item 1A under the heading â€œRisk Factors.â€ We caution investors that our business and financial performance are subject to substantial risks and uncertainties.This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in

this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.â€‹â€‹iiTable of ContentsSELECTED RISKS AFFECTING OUR BUSINESSInvesting in our common stock involves numerous risks, including the risks described in â€œPart I, Item 1A. Risk Factorsâ€ of this Annual Report on Form 10-K, any one of which could materially adversely affect our business, financial condition, results of operations, and prospects. These risks include, among others, the following:â—We have incurred significant losses and negative cash flows from operations since our inception and expect to continue to incur significant losses and negative cash flows from operations for at least the next 12 months; â—We have never generated any revenue from product sales and may never be profitable;â—There is substantial doubt about our ability to continue as a going concern. We will need to raise substantial additional funding to complete the development and commercialization of ONS-5010/LYTENAVAâ„¢ (bevacizumab-gamma) outside of the European Union (the â€œEUâ€) and United Kingdom (the â€œUKâ€) and support our operations until we are able to generate sufficient revenue from the sales of ONS-5010/LYTENAVA in the EU and UK. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations;â—Raising additional capital, including modifications to our existing convertible securities, may cause dilution to our securityholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;â—We are highly dependent on the success of ONS-5010/LYTENAVA, our only product that has been approved in the EU and UK. If ONS-5010/LYTENAVA does not receive regulatory approval outside the EU and UK, or is not successfully commercialized, our business may be harmed;â—We may need to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of product candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be harmed;â—Due to our limited resources and access to capital, we have, and will continue to need to, prioritize development of certain product candidates, and these decisions may prove to have been wrong and may harm our business;â—Clinical drug development is a lengthy and expensive process and we may encounter substantial delays in our clinical trials or may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities;â—If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates, and our existing insurance coverage may not be sufficient to satisfy any liability that may arise;â—The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for ONS-5010/LYTENAVA outside of the EU and UK or in any other indications for which we plan to develop the product, or any future product candidates, on a timely basis or at all;â—Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects;â—We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours. Other products may be approved and successfully commercialized before ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates;â—We currently have no marketing and sales organization. If we are unable to establish and maintain sales and marketing capabilities in jurisdictions for which we choose to retain commercialization rights, we may be unable to generate any revenue and will depend on the efforts of our licensing partners, if any;â—We rely on third parties to manufacture and test ONS-5010/LYTENAVA, conduct our preclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for ONS-5010/LYTENAVA outside the EU and UK, or for any other of iiiTable of Contentsour product candidates, or commercialize ONS-5010/LYTENAVA or any other of our product candidates and our business could be harmed;â—We currently engage single source suppliers for clinical trial services and multiple source suppliers for future drug substance manufacturing, fill-finish manufacturing and product testing of ONS-5010/LYTENAVA. The loss of any of these suppliers, or any future single source suppliers, could harm our business;â—If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts;â—We may become involved in lawsuits to protect or enforce any future patents, which could be expensive, time-consuming and unsuccessful;â—If we are unable to obtain and maintain effective patent rights for ONS-5010/LYTENAVA or our other Â product candidates or any future product candidates, we may not be able to prevent competitors from using technologies we consider important in the development and commercialization of ONS-5010/LYTENAVA or any future product candidates, resulting in loss of any potential competitive advantage our patents may have otherwise afforded us; â—If we are unable to maintain effective proprietary rights for ONS-5010/LYTENAVA or any future product candidates, we may not be able to compete effectively in our markets;â—If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business;â—Unfavorable global economic and political conditions could adversely affect our business, financial condition or results of operations;â—We are highly dependent on the services of our key executives and personnel, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer;â—We and certain of our officers have been named as defendants in a pending securities class action lawsuit. Certain of our officers and directors have also been named as defendants in a pending shareholder derivative action. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert managementâ€™s time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in its outcome;â—If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences, which may adversely affect our business;â—The trading price of our securities is likely to be volatile, and purchasers of our securities could incur substantial losses; andâ—GMS Ventures and Investments, or GMS Ventures, beneficially owns a significant percentage of our common stock and has the right to designate members of our board of directors and is able to exert significant control over matters subject to stockholder approval, preventing new investors from influencing significant corporate decisions. â€‹ivTable of ContentsPART IItem 1. BusinessOverviewâ€‹We are a biopharmaceutical company that is the first to receive marketing authorization for an ophthalmic formulation of ONS-5010/LYTENAVAâ„¢ (bevacizumab-gamma) for use in treating wet age-related macular degeneration, or wet AMD, in the European Union, or EU, and United Kingdom, or UK. We are developing ONS-5010/LYTENAVA to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. We are also working to receive approval and launch ONS-0510/LYTENAVA in the United States. Our initial goal is to launch directly in the EU and the UK, and in the United States, if approved, as the first and only approved ophthalmic bevacizumab for the treatment of retina conditions, including wet age-related macular degeneration, or wet AMD. Our plans also include seeking approval and launching the product in Japan and other markets, either directly or through a strategic partner, if approved. We have entered into a collaboration agreement with Cencora (formerly AmerisourceBergen Corporation) to support the commercial launch of ONS-5010/LYTENAVA in Europe and the United States. â€‹Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. In October 2022, we submitted a Marketing Authorization Application, or MAA, for ONS-5010/LYTENAVA with the European Medicines Agency (EMA). On May 27, 2024, we received a marketing authorization from the European Commission for ONS-5010/LYTENAVA for the treatment of wet AMD, which is valid throughout the European Economic Area, or EEA. The marketing authorization in the EEA provides eight years of data exclusivity and 10 years of market exclusivity. On July 8, 2024, we also received approval from the Medicine and Healthcare products Regulatory Agency (MHRA) in the UK for the treatment of wet AMD. Additionally, on December 4, 2024, the UK National Institute for Health and Care Excellence (NICE) recommended LYTENAVAâ„¢ (bevacizumab gamma), as an option for the treatment of wet AMD. Â We anticipate commencing our initial commercial launches in the EEA and UK in the first half of calendar 2025.Separately, in March 2022, we submitted a BLA with the U.S. Food and Drug Association, or the FDA, for ONS-5010/LYTENAVAâ„¢. In May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010/LYTENAVA on August 30, 2022, and in October 2022, we received confirmation from the FDA that our BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. On August 29, 2023, we received a Complete Response Letter, or CRL, in which the FDA concluded it could not approve the BLA during this review cycle due to several chemical, manufacturing and control, or CMC, issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the completion of an additional adequate and well-controlled clinical trial demonstrating the effectiveness of ONS-5010/LYTENAVA in the treatment of nAMD, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD.We agreed to conduct an additional adequate and well-controlled clinical trial following discussions with the FDA in support of our BLA for ONS-5010/LYTENAVA. In December 2023, we submitted a Special Protocol Assessment, or SPA, to the FDA for this trial (NORSE EIGHT) seeking confirmation that, if successful, it would address the FDAâ€™s requirement for a second adequate and well-controlled clinical trial to support our planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, we received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA, and in September 2024, we successfully completed enrollment in the NORSE EIGHT trial. As agreed to with the FDA in the SPA, NORSE EIGHT is a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010/LYTENAVA or 0.5 mg ranibizumab intravitreal injections. Subjects received injections at Day 0 (randomization), Week 4, and Week 8 visits, with a final follow-up visit at Week 12. In November 2024, we reported that Â ONS-5010/LYTENAVA Â did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. 1Table of ContentsThe pre-specified non-inferiority endpoint at week 8 set forth in the SPA with the FDA was measured by mean change in best corrected visual acuity (BCVA) from baseline to week 8. The difference in the means between the ONS-5010/LYTENAVA and ranibizumab in the NORSE EIGHT trial was -2.257 BCVA letters with a 95% confidence interval of (-4.044, -0.470) while the lower bound of the pre-specified non-inferiority margin in the SPA was -3.5 at a 95% confidence interval; the hypothesis of noninferiority was not met (p>0.025).Â In the intent-to-treat (ITT) primary dataset, NORSE EIGHT demonstrated a mean +4.2 letter improvement in BCVA in the ONS-5010/LYTENAVA arm and +6.3 letter improvement in BCVA in the ranibizumab arm.Â Mean change in BCVA at week 8Non-InferiorityONS-5010/LYTENAVA 1.25 mg+4.2 letters95%CI: (-4.044, -0.470)P-value: 0.0863Ranibizumab 0.5mg+6.3 lettersâ€‹At the week 8 timepoint of NORSE EIGHT, ONS-5010/LYTENAVA was generally well-tolerated with overall ocular adverse event rates comparable to ranibizumab. The safety results demonstrated in NORSE EIGHT are consistent with previously reported safety results from the NORSE ONE, NORSE TWO, and NORSE THREE clinical trials, with no cases of retinal vasculitis reported in either study arm.Â Analysis of the data is ongoing as the week 12 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. Previously, through a Type A meeting and additional interactions with the FDA in a series fo Type C and Type D meetings, we identified the approaches needed to resolve the CMC comments in the CRL and believe that we have resolved these comments. If the BLA for ONS-5010/LYTENAVA is approved, we expect to receive 12 years of regulatory exclusivity in the United States.Our BLA and MAA submissions for ONS-5010/LYTENAVA in wet AMD involved three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for our clinical program to evaluate ONS-5010/LYTENAVA as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019. In August 2020, we reported achieving the anticipated safety and efficacy proof-of-concept results from NORSE ONE, a clinical experience study. NORSE TWO was our pivotal Phase 3 clinical trial comparing ONS-5010/LYTENAVA to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010/LYTENAVA met the primary and key secondary endpoints for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in Best Corrected Visual Acuity, or BCVA, score was met and was both highly statistically significant and clinically relevant. For a discussion of NORSE TWO, please see â€œOur Product Candidate Portfolioâ€”ONS-5010/LYTENAVA â€” Bevacizumab for Ophthalmic Useâ€”Clinical Development Statusâ€”NORSE TWOâ€. In the intent to treat, or ITT, primary dataset, the percentage of patients who gained at least 15 letters who were treated with ONS-5010/LYTENAVA, was 41.7%, and the percentage of patients who gained at least 15 letters who were treated with ranibizumab was 23.1% (p = 0.0052). The primary endpoint was also statistically significant and clinically relevant in the secondary per protocol, or PP, dataset (p = 0.04) where the percentages were almost identical, at 41.0% with ONS-5010/LYTENAVA, and 24.7% with ranibizumab. The key secondary endpoint, BCVA score change from baseline to month 11, in the primary ITT dataset was also highly statistically significant and clinically relevant (p = 0.0035). A mean change of 11.2 letters in BCVA score was observed with ONS-5010/LYTENAVA, and with ranibizumab the mean change was 5.8 letters. The results were also statistically significant in the secondary PP dataset (p = 0.01) with a mean change with ONS-5010/LYTENAVA of 11.1 letters versus 7.0 letters with ranibizumab. Additionally, the majority of ONS-5010/LYTENAVA subjects maintained or gained BCVA during the study (defined as change from baseline in BCVA â‰¥ 0), with at least 80% of ONS-5010/LYTENAVA subjects maintaining BCVA each month. Results were also positive for the remaining NORSE TWO secondary endpoints with 56.5% (p = 0.0016) of ONS-5010/LYTENAVA subjects gaining â‰¥ 10 letters of vision and 68.5% (p = 0.0116) of ONS-5010/LYTENAVA subjects gaining â‰¥ 5 letters of vision. NORSE THREE was an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010/LYTENAVA were available for the initial ONS-5010/LYTENAVA BLA submission with the FDA. In March 2021, we reported that the results from NORSE 2Table of ContentsTHREE showed a positive safety profile for ONS-5010/LYTENAVA. The NORSE BLA registration program was also used to support our successful MAA submissions in the EU and UK.Additionally, in November 2021, we began enrolling patients in our NORSE SEVEN clinical trial. The study compares the safety of ophthalmic bevacizumab in vials versus pre-filled syringes in subjects diagnosed with a retinal condition that would benefit from treatment with intravitreal injection of bevacizumab, including exudative age-related macular degeneration, DME, or BRVO. Subjects will be treated for three months, and the enrollment of subjects in the arm of the study receiving ONS-5010/LYTENAVA in vials has been completed.We have also received agreement from the FDA on three SPAs for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010/LYTENAVA. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010/LYTENAVA to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010/LYTENAVA to treat DME. The timing for initiating these studies has not been determined pending initial FDA approval for wet AMD.Because there are no approved bevacizumab products for the treatment of retinal diseases in the United States, we submitted a standard BLA, and are not using the biosimilar drug development pathway that would be required if there were an approved bevacizumab drug for the targeted diseases. If approved in the United States, we believe ONS-5010/LYTENAVA has potential to mitigate risks associated with off-label use of repackaged bevacizumab. In the United States, 66.3% of retina physicians state off-label repackaged bevacizumab is their most commonly used first-line anti-VEGF (ASRS 2022 Membership Survey Presented at ASRS NY 2022).Our StrategyOur goal is to launch ONS-5010/LYTENAVA as the first, and only, approved bevacizumab for ophthalmic use in the EU, UK, United States and other markets. We plan to do this directly in the United States and either directly or through a strategic partner in the EU and UK and in other markets. In order to achieve this goal, we have adopted a streamlined clinical and regulatory strategy, the key elements of which include:â—Leveraging the ophthalmic drug development and commercialization expertise of our leadership team. Members of our executive team have extensive expertise in developing and commercializing treatments for retinal diseases, such as wet AMD, DME and BRVO. We intend to leverage their collective experience to further the development of, and execute an optimal commercial strategy for, ONS-5010/LYTENAVA, including licensing commercial rights to ONS-5010/LYTENAVA to a strategic partner outside the United States.â—Engaging with regulatory authorities to establish clear guidelines for potential approval of ONS-5010/LYTENAVA outside the EU and UK. We have continued our approach of working closely with regulatory authorities to develop and conduct clinical trials that we believe will appropriately support approval of ONS-5010/LYTENAVA outside the EU and UK.â—Leveraging the expertise of large partners in the biopharma industry to support launch of ONS-5010/LYTENAVA in the EU and UK, and outside of these countries if the product is approved in other territories. We have entered into a strategic commercialization agreement for the distribution of ONS-5010/LYTENAVA, which is intended to provide us with the leverage and capabilities of a large biopharmaceutical company. We use the same approach for leveraging the expertise of experienced third party biologic manufacturers for the production of our drug substance and finished product.â—Reducing and managing costs to

minimize additional investment to complete our development programs and plan for a potential commercial launch. We have made the strategic decision to outsource the commercial manufacturing and future clinical trial supply manufacturing for ONS-5010/LYTENAVA and other product candidates. We believe this will significantly reduce future overhead costs not directly related to our ONS-5010/LYTENAVA program.3Table of ContentsOur PipelineONS-5010/LYTENAVA â€" Bevacizumab for Ophthalmic UseWe have one product, ONS-5010/LYTENAVA, an ophthalmic formulation of bevacizumab, approved in the EU and UK. On May 27, 2024, the European Commission granted a marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD. This authorization is valid throughout the EEA. On July 8, 2024, the MHRA also granted a marketing authorization for ONS-5010/LYTENAVA in the UK for the treatment of wet AMD. ONS-5010/LYTENAVA is currently authorized for supply in vials. We also plan, however, to seek a variation to the current authorization to permit approval of supply of the product in pre-filled syringes.We are actively working towards obtaining FDA approval of ONS-5010/LYTENAVA for the treatment of wet AMD and anticipate resubmitting a BLA in the first calendar quarter of 2025. We are also planning to develop ONS-5010/LYTENAVA for use in the treatment of other retina diseases such as DME and BRVO. We continue to hold the developed market commercialization rights for two legacy biosimilar product candidates, but currently have no plans to further develop these assets.Bevacizumab is a full-length, humanized anti-VEGF recombinant mAb that inhibits VEGF and associated angiogenic (the growth of new blood vessels) activity. With wet AMD, abnormally high levels of VEGF are secreted in the eye. VEGF is a protein that promotes the growth of new abnormal blood vessels. Anti-VEGF injection therapy blocks this growth. Since the advent of anti-VEGF therapy, it has become the standard of care treatment option within the retina community, globally.Market OpportunityAge-related macular degeneration, or AMD, is a common eye condition and a leading cause of vision loss among people age 50 and older. Wet AMD is a form of â€œlate stageâ€ AMD and is also called neovascular AMD. In wet AMD, abnormal blood vessels grow underneath the retina. These vessels can leak fluid and blood, which may lead to swelling and damage of the macula causing vision loss. With wet AMD, abnormally high levels of VEGF are secreted in the eyes. VEGF is a protein that promotes the growth of new abnormal blood vessels. Anti-VEGF injection therapy blocks this growth. Since the advent of anti-VEGF therapy, it has become the standard of care treatment option within the retina community, globally. Wet AMD is a significant disease worldwide, with an estimated prevalence of over 2.9 million patients diagnosed in the United States, European countries and Japan alone in 2020 (GlobalData). Although bevacizumab is not currently FDA-approved for use in treating wet AMD, in the United States, approximately 66.3% of new patient starts are off-label repackaged bevacizumab (ASRS 2022 Membership Survey Presented at ASRS NY 2022). Similarly, prior to the marketing authorization of ONS-5010/LYTENAVA in the EU and UK, bevacizumab has been commonly utilized off-label in the treatment of wet AMD in many European countries. There is variability across European countries but in some markets it is believed that up to 80% of all wet AMD intravitreal injections are with bevacizumab. We believe ONS-5010/LYTENAVA has potential to mitigate risks associated with off-label repackaging of bevacizumab including, but not limited to, variability in potency, safety and sterility adverse events and syringe-related adverse events.DME is caused by a complication of diabetes called diabetic retinopathy. Diabetic retinopathy is the most common diabetic eye disease and the leading cause of irreversible blindness in working age Americans. Diabetic retinopathy usually affects both eyes and is caused by ongoing damage to the small blood vessels of the retina. The leakage of fluid into the retina may lead to swelling of the surrounding tissue, including the macula. DME is the most common cause of vision loss in people with diabetic retinopathy. DME can occur at any stage of diabetic retinopathy, although it is more likely to occur in later stages of the disease. There were approximately 8.6 million patients with DME in the United States, European countries and Japan alone in 2020 (GlobalData).In BRVO, retinal vein occlusions occur when there is a blockage of veins carrying blood with needed oxygen and nutrients away from the nerve cells in the retina. A blockage in the main vein of the retina is referred to as a central retinal vein occlusion, or CRVO, while a blockage in a smaller vein is called BRVO. Per the American Academy of Ophthalmology, retinal vein occlusions are the second most common retinal vascular disorder after diabetic retinopathy. There were an estimated 0.3 million patients with BRVO in the United States, European countries and Japan alone in 2020 (Triangulation 4Table of Contentsof Global Data, Market Scope and Investor Forecasts (2020)).Annual revenue (worldwide) for anti-VEGF therapies was estimated to be $13.1 billion in 2020 (GlobalData). The United States accounted for approximately 50% of this market and Europe accounted for approximately 25% in 2020 (Global Data).Clinical Development Status â€‹The study design for our Phase 3 clinical program to evaluate ONS-5010/LYTENAVA as an ophthalmic formulation of bevacizumab was reviewed with the FDA at an end of Phase 2 meeting in April 2018, and we filed our IND with the FDA in the first quarter of calendar 2019. Our registration plan for wet AMD, the initial indication planned for ONS-5010/LYTENAVA, consisted of three clinical trials which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. All three clinical trials have been completed. We reported achieving the anticipated safety and efficacy and positive proof-of-concept topline results from NORSE ONE, a clinical experience study, in August 2020. NORSE TWO was our pivotal Phase 3 clinical trial comparing ONS-5010/LYTENAVA to ranibizumab (LUCENTIS) that reported highly statistically significant topline results in August 2021. NORSE THREE was an open-label safety study conducted to ensure the adequate number of safety exposures to ONS-5010/LYTENAVA were available for the ONS-5010/LYTENAVA BLA submission with the FDA. After reviewing our BLA for ONS-5010/LYTENAVA, the FDA issued a CRL indicating that it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. We have agreed to conduct an additional clinical trial (NORSE EIGHT) to support approval of ONS-5010/LYTENAVA for the treatment of wet AMD in the United States. The FDA agreed with our SPA for NORSE EIGHT, and we successfully completed enrollment in the trial in September 2024. NORSE EIGHT is designed as a randomized, controlled non-inferiority clinical trial to assess the safety and efficacy of intravitreal injections of ONS-5010/LYTENAVA compared with ranibizumab (Lucentis) intravitreal injections, in subjects with neovascular age-related macular degeneration (nAMD). In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in SPA with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA, as described in greater detail above under â€œâ€"Overviewâ€. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025 (see â€œ-Overviewâ€).We have received agreements from the FDA on three SPAs for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010/LYTENAVA. The agreements reached with the FDA on these SPAs cover the protocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010/LYTENAVA to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010/LYTENAVA to treat DME. We intend to initiate these studies following the anticipated FDA approval of our BLA for wet AMD.In November 2021, we began enrolling patients in our NORSE SEVEN clinical trial. The study compares the safety of ophthalmic bevacizumab in vials versus pre-filled syringes in subjects diagnosed with a retinal condition that would benefit from treatment with intravitreal injection of bevacizumab, including exudative age-related macular degeneration, DME, or BRVO. Subjects will be treated for three months, and the enrollment of subjects in the arm of the study receiving ONS-5010/LYTENAVA in vials has been completed.5Table of ContentsNORSE ONENORSE ONE was designed as a randomized, masked clinical experience trial to support our BLA submission with the FDA for ONS-5010/LYTENAVA for the treatment of wet AMD. A total of 61 treatment naÃ¯ve and previously treated patients were enrolled in the study at nine sites in Australia and randomized onto treatment arms of ONS-5010/LYTENAVA or ranibizumab. The primary endpoint for the study was the difference in proportion of subjects gaining 15 letters of BCVA at Day 330 for ONS-5010/LYTENAVA dosed on a monthly basis compared to ranibizumab dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing.In August 2020, we reported positive proof-of-concept topline results for ONS-5010/LYTENAVA as it achieved anticipated safety and efficacy expectations. In the analysis of treatment naÃ¯ve patients who had a baseline visual acuity of < 67 letters (20/50 or worse) at study entry, 2 of 4 (50%) patients in the ONS-5010/LYTENAVA arm and 4 of 9 (44%) patients in the ranibizumab arm achieved > 15 letters at Day 330. This subgroup was the relevant patient population for our pivotal clinical trial of ONS-5010/LYTENAVA (NORSE TWO). Additionally, in a key secondary endpoint for the relevant patient population, the ONS-5010/LYTENAVA patients achieved a mean improvement in BCVA of 8.3 letters. NORSE TWONORSE TWO was a masked, randomized, pivotal Phase 3 clinical trial evaluating ONS-5010/LYTENAVA against ranibizumab for wet AMD. A total of 227 primarily treatment naÃ¯ve patients were enrolled at 39 clinical trial sites in the United States. Patients enrolled in the study were randomized to either ONS-5010/LYTENAVA or ranibizumab arms and were treated for 11 months. The primary endpoint for the study was the difference in proportion of subjects gaining 15 letters of BCVA at Day 330 for ONS-5010/LYTENAVA dosed on a monthly basis compared to ranibizumab dosed using the PIER alternative dosing regimen. We reported topline results for NORSE TWO in August 2021.The topline results reported from NORSE TWO in August 2021 showed that ONS-5010/LYTENAVA met the primary and key secondary endpoint for efficacy with clinically impactful change observed for treated patients. The NORSE TWO primary endpoint difference in proportion of subjects gaining at least 15 letters in BCVA score was met and was both highly statistically significant and clinically relevant. In the intent-to-treat, or ITT, primary dataset, the percentage of patients who gained at least 15 letters who were treated with ONS-5010/LYTENAVA, was 41.7%, and the percentage of patients who gained at least 15 letters who were treated with ranibizumab was 23.1% (p = 0.0052). The primary endpoint was also statistically significant and clinically relevant in the secondary per-protocol, or PP dataset (p = 0.04) where the percentages were almost identical, at 41.0% with ONS-5010/LYTENAVA, and 24.7% with ranibizumab. The key secondary endpoint BCVA score change from baseline to month 11 in the primary ITT dataset was also highly statistically significant and clinically relevant (p = 0.0035). A mean change of 11.2 letters in BCVA score was observed with ONS-5010/LYTENAVA, and with ranibizumab the mean change was 5.8 letters. The results were also statistically significant in the secondary PP dataset (p = 0.01) with a mean change with ONS-5010/LYTENAVA of 11.1 letters versus 7.0 letters with ranibizumab. Results were also positive for the remaining NORSE TWO secondary endpoints with 56.5% (p = 0.0016) of ONS-5010/LYTENAVA subjects gaining â‰¥ 10 letters of vision and 68.5% (p = 0.0116) of ONS-5010/LYTENAVA subjects gaining â‰¥ 5 letters of vision. 6Table of Contentsâ€‹â€‹NORSE THREENORSE THREE was an open-label safety study we conducted to ensure the adequate number of safety exposures to ONS-5010/LYTENAVA were available for the initial ONS-5010/LYTENAVA BLA submission with the FDA. In March 2021 we reported that the results from NORSE THREE provided a positive safety profile for ONS-5010/LYTENAVA.NORSE SEVENNORSE SEVEN was initiated to support our ongoing development program for delivering ONS-5010/LYTENAVA using a pre-filled syringe. It is a three month study designed to compare the safety of ophthalmic bevacizumab in vials versus 7Table of Contentspre-filled syringes in subjects diagnosed with a retinal condition that would benefit from treatment with intravitreal injection of bevacizumab, including exudative AMD, DME, or BRVO. A total of 120 patients are expected to be enrolled in the study with 60 patients receiving ONS-5010/LYTENAVA packaged in vials and 60 patients receiving ONS packaged in a pre-filled syringe. Subjects will be treated for three months and the enrollment of subjects in the arm of the study receiving ONS-5010/LYTENAVA in vials has been completed. If successful, this study will support the submission of a supplemental BLA to the FDA after ONS-5010/LYTENAVA is approved for wet AMD.NORSE EIGHTNORSE EIGHT is a randomized, controlled, parallel-group, masked non-inferiority study of neovascular age-related macular degeneration subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010/LYTENAVA or 0.5 mg ranibizumab intravitreal injections. The primary endpoint is the mean change in BCVA from baseline to Week 8. Subjects received injections at Day 0 (randomization), Week 4, and Week 8 visits. In January 2024, we received confirmation from the FDA that, if successful, this study will address the FDAâ€™s requirement for a second adequate and well-controlled clinical trial to support the resubmission of the ONS-5010/LYTENAVA BLA for wet AMD. â€‹A total of 400 patients were enrolled in the study. We successfully completed enrollment in September 2024 and in November 2024 we reported that Â ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010. The difference in the means between the ONS-5010/LYTENAVA and ranibizumab in the NORSE EIGHT trial was -2.257 BCVA letters with a 95% confidence interval of (-4.044, -0.470) while the lower bound of the pre-specified non-inferiority margin in the SPA was -3.5 at a 95% confidence interval; the hypothesis of noninferiority was not met (p>0.025). In the intent-to-treat (ITT) primary dataset, NORSE EIGHT demonstrated a mean +4.2 letter improvement in BCVA in the ONS-5010/LYTENAVA arm and +6.3 letter improvement in BCVA in the ranibizumab arm. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025.â€‹Commercialization, Sales and MarketingOur commercialization strategy is to provide a safe, effective, and affordable on-label bevacizumab for the retina community while maximizing revenue and patient access to ONS-5010/LYTENAVA. As part of our multi-year commercial planning process, we entered into a strategic collaboration agreement with Cencora to support the commercial launch of ONS-5010/LYTENAVA globally. Cencora will provide comprehensive launch support in the EU and UK, including pharmacovigilance, regulatory affairs, quality management, market access support, importation, third-party logistics distribution and field solutions. The collaboration and integrated approach is designed to support market access and efficient distribution of ONS-5010/LYTENAVA in the EU and UK, as well as other regions outside the United States. If approved by the FDA, we currently intend to launch and market ONS-5010/LYTENAVA ourselves in the United States. We currently own all of the development and commercialization rights to ONS-5010/LYTENAVA and have licensed rights only to our joint venture in the Peopleâ€™s Republic of China, or PRC, for the greater China market (see â€œ-Collaboration and License Agreements-Syntone-Private Placement and PRC Joint Ventureâ€). The marketing authorization for ONS-5010/LYTENAVA in the EEA provides eight years of data exclusivity and 10 years of market exclusivity. If approved by the FDA, we believe that ONS-5010/LYTENAVA will be entitled to 12 years of regulatory exclusivity granted in the United States against biosimilar competition.â€‹For many years, anti-VEGF therapy has been the standard of care for many ophthalmic diseases, including wet AMD, DME and BRVO. However, although multiple branded drugs have been approved for these indications (e.g., LUCENTIS, EYLEA, EYLEA HD, BEOVU, SUSVIMO and VABYSMO), they are very expensive. The recently approved biosimilar versions of LUCENTIS and EYLEA are also expensive, although they are available at a discount to the reference drug. Doctors who wish to treat their retinal patients with a less expensive anti-VEGF drug, with minimal reimbursement hurdles, often use off-label bevacizumab. However, because there is no FDA approved ophthalmic formulation of bevacizumab in the United States, and there was previously no approved ophthalmic formulation of bevacizumab in the EU or UK until the marketing authorizations of ONS-5010/LYTENAVA in the EU and UK, doctors have used repackaged bevacizumab (Avastin) provided by compounding pharmacists that is not required to meet the standards for ophthalmic 8Table of Contentsuse necessary for an approved product. Despite cliniciansâ€™ widespread acceptance and use of bevacizumab to treat ophthalmic diseases such as wet AMD, DME and BRVO, no manufacturer has previously sought approval of bevacizumab for these diseases.The repackaged bevacizumab that is provided by compounding pharmacies is not required to meet ophthalmic drug standards and can carry known risks of contamination (including silicone oil droplet contamination from syringes) and inconsistent potency, with potentially severe consequences, as leading retinal societies have reported. For these reasons, the retina community and payors have shown interest in the development of an ophthalmic formulation of bevacizumab that could be an on-label alternative to repackaged bevacizumab from compounding pharmacists. Of 152 U.S. and European retina physicians surveyed in 2019, nearly 84% indicated they had an interest or high interest in an approved ophthalmic formulation of bevacizumab. To meet this retinal market need, we are developing ONS-5010/LYTENAVA as an investigational ophthalmic formulation of bevacizumab in the United States. ONS-5010/LYTENAVA has been approved for the treatment of wet AMD in the EU and UK and provides a viable treatment option across the spectrum of anti-VEGF ophthalmic drugs that treat wet AMD, avoiding the safety, sterility, potency, availability, and syringe drawbacks that can occur with repackaged bevacizumab from compounding pharmacies. If approved in other indications, ONS-5010/LYTENAVA may also provide a viable alternative for the treatment of DME and BRVO. â€‹Furthermore, we expect that ONS-5010/LYTENAVA will be able to help mitigate the high cost of treatment for retinal diseases in the EU and UK, and also in the United States if the product is approved there. Both in the United States and globally, the high cost of treating retinal diseases such as wet AMD, DME and BRVO can result in patients receiving an insufficient number of treatments, or potentially no treatment at all. We believe in the value of having an affordable, FDA and European Commission-approved option for patients that is safe, effective, and manufactured under proper guidance. Our commercial strategy for ONS-5010/LYTENAVA includes providing an on-label bevacizumab as a first line option for treating retinal diseases. In addition, our approach to responsible price determination is being crafted with the retina community (patients, payors, and providers) to support patient access, maintain physician choice, and accelerate time to treatment. We are committed to keeping the patient at the core of what we do to ensure we provide an affordable option that offers streamlined access to compliant patient support services.ONS-5010/LYTENAVA has the potential to become the anti-VEGF cornerstone of care for retinal diseases in the EU and UK, and also in the United States if the product is approved there. It may also provide synergies with future long-acting agents and adjunct therapies for advanced treatment of wet AMD, DME and BRVO. ONS-5010/LYTENAVA has the potential to help lower the aggregate costs of treating retinal diseases for the overall healthcare system in the EU and UK, and in the United States if the product is approved and commercialized there.â€‹Collaboration and License AgreementsWe enter into collaboration and license agreements in the ordinary course of our business. We have in-licensed certain technology from Selexis SA, or Selexis, that we used to research and develop our product candidates. For product

candidates developed using the Selexis technology, we enter into commercial license agreements with Selexis that give us rights to commercialize, file investigational new drugs, or INDs and enter into collaborative arrangements with third parties for the further development and commercialization of such biosimilar product candidates. Although we are no longer working on our biosimilar development program, we have licensed rights to these biosimilar product candidates (ONS-3010, ONS-1045 and ONS-1050) in other markets.Syntone â€“ Private Placement and PRC Joint VentureIn May 2020, we entered into a stock purchase agreement with Syntone Ventures LLC, or Syntone, pursuant to which we sold and issued, in a private placement in June 2020, 800,000 shares of our common stock at a purchase price of $20.00 per share, for aggregate gross proceeds of $16.0 million. In connection with the entry into the stock purchase agreement, we entered into a joint venture agreement with Syntoneâ€™s PRC-based affiliate, pursuant to which we agreed to form a PRC joint venture that is 80% owned by Syntoneâ€™s PRC-affiliate and 20% owned by us. Upon formation of the PRC joint venture in April 2021, we entered into a royalty-free license with the PRC joint venture for the development, 9Table of Contentscommercialization and manufacture of ONS-5010/LYTENAVA in the greater China market, which includes Hong Kong, Taiwan and Macau.We used approximately $0.9 million of the proceeds from the May 2020 private placement to Syntone to fund our initial capital contribution to the PRC joint venture, and are committed to make additional capital contributions to the PRC joint venture up to approximately $2.1 million which will be made within four years after the establishment date (April 2021) upon approval of the development plan contemplated in the license agreement or on such other terms as may be determined within such four-year period.SelexisIn October 2011, Selexis granted us a non-transferrable option to obtain a perpetual, non-exclusive, worldwide commercial license under the Selexis Technology to manufacture, or have manufactured, a recombinant protein produced by a cell line developed using the Selexis Technology for clinical testing and commercial sale. We exercised this option in April 2013 and entered into three commercial license agreements with Selexis for ONS-1045 (which covers ONS-5010/LYTENAVA), and two of our biosimilar product candidates, ONS-3010 and ONS-1050 (which are no longer in active clinical development). We paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sub-licensees during the royalty term. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee.Commercial License AgreementsOn April 11, 2013, following the exercise of our option to enter a commercial license under the Selexis research license, we entered into commercial license agreements with Selexis for each of ONS-1045, ONS-3010 and ONS-1050. Under the terms of each commercial license agreement, we acquired a non-exclusive worldwide license under the Selexis Technology to use the cell lines developed under the research license and related materials, to manufacture and commercialize licensed and final products, with a limited right to sublicense.We were required to pay an upfront licensing fee of CHF 65,000 (approximately $0.1 million) to Selexis for each commercial license and also agreed to pay up to CHF 365,000 (approximately $0.4 million) in milestone payments for each licensed product. In addition, we are required to pay a single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by us or any of our affiliates or sublicensees during the royalty term. The royalty term for each final product in each country is the period commencing from the first commercial sale of the applicable final product in the applicable country and ending on the expiration of the specified patent coverage. At any time during the term, we have the right to terminate our royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee of CHF 1,750,000 (approximately $1.8 million). The initiation of our Phase 3 clinical program for ONS-5010/LYTENAVA in fiscal 2019 triggered a CHF 65,000 (approximately $0.1 million) milestone payment to Selexis under the commercial license agreement, which we paid in November 2019. As of September 30, 2024, we have paid Selexis an aggregate of approximately $0.4 million under the commercial license agreements.Each of our commercial agreements with Selexis will expire in its entirety upon the expiration of all applicable Selexis patent rights. The licensed patent rights consist of two patent families. The first patent family relates to methods of transferring cells, and is filed in the United States, Australia, Canada, Europe, Japan and Singapore. This patent family began to expire worldwide in 2022. The second patent family claims DNA compositions of matter useful for having protein production increasing activity. This patent family is filed in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Russia, Singapore and South Africa. This patent family will begin to expire worldwide in 2025. Either party may terminate the related agreement in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, winding up or similar circumstances.Either party may also terminate the related agreement under designated circumstances if the Selexis Technology infringes third-party intellectual property rights. In addition, we have the right to terminate each of the commercial agreements at 10Table of Contentsany time for our convenience; however, with respect to the agreements relating to ONS-3010 and ONS-1045, this right is subject to the consent of Laboratories Liomont, S.A. de C.V., or Liomont (a licensing partner in Mexico for ONS-3010 and ONS-1045) pursuant to a corresponding letter we executed in conjunction with the standby agreement entered into between Selexis and Liomont on November 11, 2014. The standby agreement permits Liomont to assume the license under the applicable commercial agreement for Mexico upon specified triggering events involving our bankruptcy, insolvency or similar circumstances.ManufacturingWe are working with FujiFilm Diosynth Biotechnologies, or Fuji, and Ajinomoto Bio-pharma Services, or AjiBio, to provide product manufacturing in current Good Manufacturing Practices, or cGMP, manufacturing facilities. We have also executed a supply agreement for a best-in-class pre-filled ophthalmic syringe, which we believe will provide both ease-of-use for clinicians and add to ONS-5010/LYTENAVAâ€™s safety profile over the current unapproved therapies that have caused problems related to syringe malfunction and contamination. We will screen other contract manufacturers to meet our clinical, commercial and regulatory supply requirements as needed. For a discussion of risks related to our sources and availability of supplies, please see â€œRisk Factors.â€ Previously, we manufactured bulk drug substance for preclinical and clinical supplies of our product candidates in our in-house facility. Our business could be harmed if our current contract manufacturer is unable to manufacture our product candidates at the necessary quantity or quality levels, We currently engage single source suppliers for clinical trial services and multiple source suppliers for future drug substance manufacturing, fill-finish manufacturing and product testing of ONS-5010/LYTENAVA. The loss of any of these suppliers, or any future single source suppliers, could harm our business.CompetitionCompetition in the area of pharmaceutical research and development is extensive and significantly depends upon multiple scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain regulatory approval for testing, manufacturing and marketing. Our competitors include major pharmaceutical and specialized biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours, as well as compounding pharmacies that repackage bevacizumab to treat retinal diseases. In addition, many biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours, and we may also compete against other biotechnology companies in our efforts to find a potential strategic partner for ONS-5010/LYTENAVA. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain other products manufactured or under development by competitors that are used for the treatment of the health conditions that we have targeted for product development. We can provide no assurance that developments by others will not render our technology obsolete, noncompetitive or harm our development strategy, that we will be able to keep pace with new technological developments, that our technology will be able to supplant established products and methodologies in the therapeutic areas that are targeted by us or that we will be able to enter into a strategic partnership arrangement for ONS-5010/LYTENAVA. The foregoing factors could have a material adverse effect on our business, prospects, financial condition and results of operations. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants.We will encounter competition from existing firms that offer competitive solutions in ocular diseases. These competitive companies could develop products that are superior to, or have greater market acceptance than the product candidates being developed by us. We will have to compete against other biotechnology and pharmaceutical companies with greater market recognition and greater financial, marketing and other resources.Wet-AMD Market â€‹AMD is a medical condition that usually affects older adults and generally results in a loss of vision. AMD occurs in â€œdryâ€ (non-exudative) and â€œwetâ€ (exudative) forms. Wet AMD is the advanced form of macular degeneration that involves the formation of abnormal and leaky blood vessels in the back of the eye behind the retina, through a process known as 11Table of Contentschoroidal neovascularization. While the wet form accounts for approximately 15% of all AMD cases, according to the National Eye Institute, it is responsible for 90% of severe vision loss associated with AMD. The National Eye Institute also estimates that the prevalence of wet AMD among adults 40 years or older in the United States is approximately 1.75 million people. In addition, more than 200,000 new cases are diagnosed annually in North America. Similary, it is estimated that the prevalence of wet AMD in Europe is approximately 1.7 million people. Globally, the incidence and prevalence of wet AMD is projected to increase significantly in the future due to an aging population.Competitive LandscapeIn the United States, approximately 66.3% of new patient starts are off-label repackaged bevacizumab (ASRS 2022 Membership Survey Presented at ASRS NY 2022). Off-label repackaged bevacizumab is also commonly utilized in the treatment of wet AMD in Europe. The current FDA approved market leaders for the treatment of wet AMD are VEGF inhibitors, including EYLEA, EYLEA HD, BEOVU, LUCENTIS, SUSVIMO and VABYSMO. Recently, BYOOVIZ and CIMERLI were approved and launched, both ranibizumab biosimilars, as well as PAVBLU, an aflibercept biosimilar. Annual revenue (worldwide) for anti-VEGF therapies was estimated to be $13.1 billion in 2020 (Triangulation of Global Data, Market Scope and Investor Forecasts (2020)). We expect to strategically price ONS-5010/LYTENAVA to make it a lower cost alternative to biosimilars and premium branded products, while higher than off-label compounds. The initial recently approved biosimilar versions of LUCENTIS and EYLEA are also expensive, although they are available at a discount to the reference drug. Bevacizumab, BYOOVIZ, CIMERLI, PAVBLU, EYLEA, EYLEA HD, BEOVU, LUCENTIS and VABYSMO are all administered via intravitreal injections directly into the eye. SUSVIMO is an implantable refillable port delivery system that delivers anti-VEGF for 4-6 months, upon which the device is refilled. In addition to the other treatments used in patients with wet AMD, there are various other companies with product candidates in Phase 1, 2 and 3 clinical trials, or FDA review, for the treatment of wet AMD. Programs currently in Phase 2 or Phase 3 clinical trials or FDA review include, but are not limited to:â€‹â—Bevacizumab (HLX04-O) under development by Shanghai Henlius Biotech, Inc. and Essex Bio-Technology Ltd;â—Ranibizumab biosimilar developed by STADA Arzneimittel AG and Xbrane Biopharma AB;â—Aflibercept biosimilars developed by Bioeq/Formycon (FB-203), Mylan (M-710) and Samsung/Biogen (SB-15) among others;â—Small molecule receptor tyrosine kinase inhibitor sunitinib malate (Graybug, GB-102); andâ—Adeno-associated virus (AAV) carrying aflibercept coding sequence (Adverum, ADVM-022).We believe that ONS-5010/LYTENAVA has potential competitive advantages due to the familiarity of physicians in using off-label Avastin. We also believe that an affordable, FDA and European Commission-approved ophthalmic bevacizumab option, that is safe, effective, and manufactured under proper guidance will garner strong market uptake and patient access to therapy. Furthermore, we have reduced the risk in our clinical program by leveraging our prior work in developing a biosmilar drug product candidate for Avastin as a treatment for cancer. However, clinical trial data from other clinical programs may negatively impact our ability to garner future financing or business collaborations, combinations or transactions with other pharmaceutical and biotechnology companies.Intellectual PropertyOur commercial success depends in part on our ability to avoid infringing the proprietary rights of third parties, our ability to obtain and maintain proprietary protection for our technologies where applicable and to prevent others from infringing our proprietary rights. We seek to protect our proprietary technologies by, among other methods, evaluating relevant patents, establishing defensive positions, monitoring EU oppositions and pending intellectual property rights, preparing litigation strategies in view of the U.S. legislative framework and filing U.S. and international patent applications on technologies, inventions and improvements that are important to our business. As of September 30, 2024, we own three U.S. patents, eighteen foreign patents, and two pending international applications that were nationalized from six Patent Cooperation Treaty, or PCT, applications, which relate to formulations developed for our legacy biosimilar program ONS-3010 and ONS-5010/ONS-1045, methods of antibody purification, methods for purifying antibodies to separate isoforms, methods of use, methods of reducing high molecular weight species, and modulating afucosylated species as well as efficiently determining the amino acid sequence of antibodies. Our first PCT application was nationalized in April 2016 in Australia, Canada, China, Europe, Hong Kong, India, Japan, Mexico and the United States. If granted, patents issuing 12Table of Contentsfrom these nine applications are expected to expire in 2034, absent any adjustments or extensions. Our second PCT application was nationalized in July 2017 in Europe and the United States. If granted, patents issuing from these two applications are expected to expire in 2036, absent any adjustments or extensions. Our third PCT application was nationalized in June 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2036, absent any adjustments or extensions. Our fourth PCT application was nationalized in July 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Our fifth PCT application was nationalized in August 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. Our sixth PCT application was nationalized in August 2018 in Australia, Canada, China, Europe, India, Japan, Mexico and the United States. If granted, patents issuing from these eight applications are expected to expire in 2037, absent any adjustments or extensions. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.The term of individual patents depends upon the legal term of the patents in countries in which they are obtained. In most countries, including the United States, the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the United States, a patentâ€™s term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.RegulatoryGovernment Regulation and Product ApprovalThe FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:â—completion of preclinical laboratory tests and animal studies performed in accordance with the FDAâ€™s current Good Laboratory Practices, or GLP, regulation;â—submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;â—approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;â—performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;â—preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;â—a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;â—satisfactory completion of an FDA Advisory Committee review, if applicable;13Table of Contentsâ—satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological productâ€™s continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; andâ—FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.Preclinical and Clinical DevelopmentPrior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with

GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.â—Phase 1 â€" The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.â—Phase 2 â€" The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.â—Phase 3 â€" The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.14Table of ContentsIn some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.BLA Submission and ReviewAssuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the productâ€™s chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.Once a BLA has been submitted, the FDAâ€™s goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the productâ€™s continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches 15Table of Contentsthe marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance to further assess and monitor the productâ€™s safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.Post-Approval RequirementsAny products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.The FDA may 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 a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, 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 studies 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 a product, complete withdrawal of the product from the market or product recalls;â—fines, warning letters or holds on post-approval clinical studies;â—refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;â—product seizure or detention, or refusal of the FDA to permit the import or export of products; orâ—injunctions or the imposition of civil or criminal penalties.The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA 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. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the productâ€™s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturerâ€™s communications on the subject of off-label use of their products.16Table of ContentsBiosimilars and Reference Product ExclusivityThe Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, 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 relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicantâ€™s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.Other U.S. Healthcare Laws and Compliance RequirementsAlthough we currently do not have any products on the market, our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors expose us to broadly applicable healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in cash or in kind, either to induce or award the referral of an individual, for an item or service or the purchasing, recommending or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on, in certain cases, sham consulting and other financial arrangements with physicians. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to commit a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or federal civil monetary penalties statute.Additionally, the federal false claims and civil monetary penalties laws, including the civil False Claims Act prohibit, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government, or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government has used the civil False Claims Act, 17Table of Contentsand the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other illegal sales and marketing practices.The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, imposes requirements regarding the privacy and security of individually identifiable health information, including mandatory contractual terms, for covered entities, or certain healthcare providers, health plans, and healthcare clearinghouses, their business associates that provide services to the covered entity that involve individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA.In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, via the Physician Payments Sunshine Act, imposes annual reporting requirements on certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Childrenâ€™s Health Insurance Program, with specific exceptions, for payments made by them to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.Certain states also impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. Certain states and local governments require the registration of pharmaceutical sales representatives. Additionally, analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. State laws may also apply that require pharmaceutical companies to comply with the pharmaceutical industryâ€™s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers or other potential referral sources. In addition, certain states require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing. In addition, state and local laws may require the registration of pharmaceutical sales representatives. We may also be subject to state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other

governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.18Table of ContentsHealthcare ReformIn the United States and some foreign jurisdictions there have been, and we expect there will continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system to contain costs, improve quality, and expand access to care. For example, in March 2010, President Obama signed into law the Affordable Care Act, which among other things, expanded coverage for the uninsured while at the same time containing overall healthcare costs, expanded and increased industry rebates for drugs covered under Medicaid programs, and made changes to the coverage requirements under the Medicare prescription drug benefit. There have been judicial, Congressional and executive branch challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the â€œindividual mandateâ€ was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the â€œdonut holeâ€ under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. Accordingly, we continue to evaluate the effect that the Affordable Care Act has on our business. Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 led to automatic reductions of Medicare payments to providers of up to 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments will remain in effect until 2032 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drugâ€™s average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. In addition, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In July 2021, the Biden administration released an executive order, â€œPromoting Competition in the American Economy,â€ with multiple provisions aimed at prescription drugs. In response to Bidenâ€™s executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated â€œmaximum fair priceâ€ under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to fifteen additional drugs covered under Part D for negotiation in 2025. Further, in response to the Biden administrationâ€™s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare and Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-19Table of ContentsIn Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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 cannot predict what healthcare reform initiatives may be adopted in the future, particularly in light of the U.S. presidential and Congressional elections. Â The Affordable Care Act, the IRA, as well as other federal, state and foreign healthcare reform measures that have been and may be adopted in the future, could harm our future revenues.International RegulationIn addition to regulations in the United States, foreign regulations also govern clinical trials, commercial sales and distribution of product candidates within their jurisdiction. The regulatory approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA approval. Clinical Trials in the EUSimilarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls. In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20, or CTD.â€‹The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. â€‹The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. For clinical trials in relation to which an application for approval was made on the basis of the CTD before January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.â€‹In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials, including ATMPs, must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.â€‹EU Review and approval processâ€‹In the EU, medicinal products can only be commercialized after a related marketing authorization, or MA, has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application, or MAA, either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the 20Table of Contentsprocedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU. â€‹The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA (which is comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval. â€‹Under the centralized procedure, the EMAâ€™s Committee for Medicinal Products for Human Use, or CHMP, conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. â€‹Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. â€‹Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agenciesâ€™ Coordination Group for Mutual Recognition and Decentralised Procedures â€“ Human, or CMDh, for review. The subsequent decision of the European Commission is binding on all EU Member States. â€‹The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State. â€‹An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause). â€‹21Table of ContentsInnovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMAâ€™s support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. â€‹In the EU, a â€œconditionalâ€ MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed. â€‹An MA may also be granted â€œunder exceptional circumstancesâ€ where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA â€œunder exceptional circumstancesâ€ is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable. â€‹Pediatric Development in the EUâ€‹In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMAâ€™s Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.â€‹22Table of ContentsManufacturing Regulation in the EUâ€‹In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case

of non-compliance with the EU or EU Member Statesâ€™ requirements applicable to the manufacturing of medicinal products.â€‹Data and Market Exclusivityâ€‹The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovatorâ€™s data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovatorâ€™s data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EUâ€™s regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.â€‹[In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.]â€‹Post-authorization Requirements in the EUâ€‹Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.â€‹All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.â€‹In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member Statesâ€™ laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. 23Table of ContentsHowever, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the productâ€™s Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.â€‹United Kingdom â€‹The UKâ€™s withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, orMHRA, is now the UKâ€™s standalone regulator for medicinal products and medical devices. Â Great Britain (England, Scotland and Wales) is now a third country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules until the implementation of the Windsor Framework.â€‹The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials, and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine how closely the UK regulations will align with the CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.â€‹Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland will remain within the scope of EU authorizations in relation to centrally authorized medicinal products until the implementation of the Windsor Framework. Accordingly, from when the Windsor Framework is implemented in Northern Ireland (currently anticipated to be January 1, 2025), products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain. To be used, sold, or supplied in Great Britain, a medicinal product must have been granted a marketing authorization that is effective in Great Britain. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. Following Brexit, the MHRA has also introduced changes to national marketing authorization procedures. There are two national routes to approval, the 150-day assessment procedure (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis.Â After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops).Â â€‹In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g. the regulatory in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. Â The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK or Great Britain.Â Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the 24Table of Contentstrusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval hasnâ€™t been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.Â â€‹In the UK, the initial duration of an MA is five years and following renewal will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal.Â Any authorization which is not followed by the actual placing of the drug on the market in the UK (or Great Britain, if the MA is only valid in Great Britain) within three (3) years shall ease to be in force.The UK has an initiative known as the Innovative Licensing and Access Pathway, orILAP which has similar aims to the EU PRIME scheme but significant differences.Â ILAP can be entered into earlier, notably during non-clinical development. The MHRA and, notably, the National Institute for Health and Care Excellence (the body responsible for assessing which medicines should be funded by the NHS in England and Wales) will assist with the development of a target development profile for medications accepted into ILAP.Pharmaceutical Coverage, Pricing and ReimbursementIn the United States and other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and the adequacy of reimbursement from third-party payors, including government health administrative authorities, managed care organizations, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost effectiveness of drug products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly drug products. A payorâ€™s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, there is no uniform policy for coverage and reimbursement in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As such, one payorâ€™s determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to realize an appropriate return on our investment in product development. Obtaining and maintaining adequate reimbursement for our product candidates, once approved, may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement compared to existing approved biologics and other therapies. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs in the United States, and coverage may be more limited than the indications for which the product is approved by the FDA or similar regulatory authorities outside the United States. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician utilization of our products and have a material adverse effect on our sales, results of operations and financial condition.â€‹In Europe, pricing and reimbursement schemes vary widely from country to country. For example, some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. In addition, the EU provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product, may adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA, process is the procedure according to which the assessment of the public health impact, 25Table of Contentstherapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. â€‹Privacy Laws In the ordinary course of our business, we may process personal or sensitive data, including data related to our clinical trials. Â Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Â Such obligations may include, without limitation, the California Consumer Privacy Act of 2018, or the CCPA, as amended, the EUâ€™s General Data Protection Regulation 2016/679, or the EU GDPR, the EU GDPR as it forms part of UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or the UK GDPR, collectively the GDPR. The CCPA and GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. These laws impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances. â€‹Additional RegulationIn addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.â€‹We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future. â€‹Employees and Human Capital ResourcesAs of September 30, 2024, we had 23 full-time employees, seven of whom were primarily engaged in research and development activities and five of whom have a Ph.D. degree. None of our employees are represented by a labor union or covered by a collective bargaining agreement.Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.26Table of ContentsCorporate InformationWe initially incorporated in January 2010 in New Jersey as Oncobiologics, Inc., and in October 2015, we reincorporated in Delaware by merging with and into a Delaware corporation. In November 2018, we changed our name to Outlook Therapeutics, Inc. Our headquarters are located at 111 S. Wood Avenue, Unit #100, Iselin, New Jersey, 08830, and our telephone number at that location is (609) 619-3990. Our website address is www.outlooktherapeutics.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into this Annual Report on Form 10-K.Item 1A. Risk Factorsâ€‹You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be adversely affected. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may adversely affect our business, financial condition, results of operations and/or prospects.Risks Related to Our Financial Condition and Capital RequirementsWe have incurred significant losses and negative cash flows from operations since our inception and expect to continue to incur significant losses and negative cash flows from operations for at least the next 12 months.We have incurred net losses in each year since our inception in January 5, 2010, including net losses of $75.4 million and $59.0 million for the years ended September 30, 2024 and 2023, respectively. We have not generated material revenue from the sales of any product. Our success as a company is substantially dependent on our ability to generate revenue from the sales of ONS-5010/LYTENAVA, which has been approved for the treatment of wet AMD in the EU and UK.We have devoted substantially all of our financial resources to identify, develop and manufacture our product candidates, including conducting, among other things, analytical characterization, process development and manufacture, formulation and clinical trials, regulatory filing and communication activities and providing general and administrative support for these operations. To date, only one of our product candidates, ONS-5010/LYTENAVA, has been approved for sale in the EU and UK, and we have financed our operations primarily through the sale of equity securities and debt financings, as well as to a limited degree, payments under our co-development and license agreements. The amount of our future net losses will depend, in part, on our ability to generate revenue from product sales, the rate of our future expenditures and our ability to obtain funding through equity or debt financing or our ability to enter into and

receive funding under strategic licensing or co-development collaborations.We expect to continue to incur significant expenses and operating losses for at least the next 12 months. We anticipate that our expenses may increase substantially if and as we:â—prepare to launch and market ONS-5010/LYTENAVA in the EU and UK, and in other countries if the product is approved in these territories;â—continue the clinical development of ONS-5010/LYTENAVA;â—advance ONS-5010/LYTENAVA into additional clinical trials;â—change or add contract manufacturing providers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;â—seek regulatory and marketing approvals for ONS-5010/LYTENAVA in the United States and other markets if we successfully complete clinical trials;27Table of Contentsâ—establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and for which we retain such rights;â—seek to identify, assess, acquire or develop other product candidates that may be complementary to ONS-5010/LYTENAVA;â—make upfront, milestone, royalty or other payments under any license agreements;â—seek to create, maintain, protect and expand our intellectual property portfolio;â—engage in litigation, including the pending securities class action lawsuit, as well as any other potential litigation;â—seek to attract and retain skilled personnel;â—create additional infrastructure to support our operations as a public company and any future commercialization efforts; andâ—experience any delays or encounter issues with any of the above, including but not limited to failed clinical trials, conflicting results, safety issues or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies in order to pursue marketing approval.Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in our value could also cause you to lose all or part of your investment.We have never generated any revenue from product sales and may never be profitable.We have one product, ONS-5010/LYTENAVA, approved for commercialization in the EU and UK and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, ONS-5010/LYTENAVA for the treatment of wet AMD, and our other targeted indications, and as appropriate, any of our other product candidates. We currently estimate that we could potentially begin generating revenue from product sales in Europe as early as the first half of calendar 2025, but this depends heavily on our success in many areas, including but not limited to:â—Securing capital sufficient to fund our commercialization efforts; â—launching and commercializing ONS-5010/LYTENAVA and any other product candidates for which we or our partners obtain regulatory and marketing approval;â—maintaining and obtaining regulatory and marketing approvals for ONS-5010/LYTENAVA and any other product candidates for which we or our partners complete clinical trials;â—retaining our manufacturing partner for ONS-5010/LYTENAVA and any approved product candidates to support clinical development, regulatory requirements and the market demand for any such approved product candidates;â—obtaining third-party coverage and adequate reimbursements of ONS-5010/LYTENAVA and any other product candidates, if approved;â—obtaining market acceptance of ONS-5010/LYTENAVA and any other product candidates for which we obtain regulatory and marketing approval as viable treatment options;28Table of Contentsâ—establishing or demonstrating in the medical community the safety and efficacy of ONS-5010/LYTENAVA and its potential advantages over and side effects compared to existing products used to treat wet AMD;â—negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;â—maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;â—attracting, hiring and retaining qualified personnel; andâ—completing clinical development of ONS-5010/LYTENAVA for the treatment of wet AMD in the United States and the other targeted indications, and any other product candidates we may develop in the future.We anticipate incurring significant costs to commercialize ONS-5010/LYTENAVA and any of our other product candidates that may be approved for commercialization in the future. Our expenses could increase beyond our expectations if we are required by the FDA, or other regulatory authorities, supranational, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, preclinical or other types of studies in addition to those that we currently anticipate. Our ability to generate revenue from the sales of ONS-5010/LYTENAVA in the EU, UK or in any other country where the product is approved, or in relation to any other product candidate that may be approved, will be dependent, in part, upon:â—our ability to execute our sales and marketing strategy for ONS-5010/LYTENAVA in the EU and UK;â€‹â—our ability to maintain and manage the necessary sales, marketing and other capabilities and infrastructure that are required to successfully commercialize ONS-5010/LYTENAVA in the EU and UK;â€‹â—the size of the markets in the territories for which we gain regulatory approval;â—the number of competitors in such markets;â—the market acceptance of ONS-5010/LYTENAVA and any other product candidate that may be approved;â—the accepted price for the product;â—the ability to obtain coverage and adequate reimbursement for ONS-5010/LYTENAVA and any other product candidate that may be approved;â—the quality and performance of ONS-5010/LYTENAVA and any other product candidate that may be approved, including the relative safety and efficacy; andâ—whether we own, or have partnered, the commercial rights for that territory.If the market for ONS-5010/LYTENAVA or any other product candidates we may develop in the future, or our share of that market, is not as large as we expect, the number of indications approved by regulatory authorities is narrower than we expect or the target population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products to become profitable. If we are unable to successfully complete development and obtain regulatory approval for ONS-5010/LYTENAVA outside the EU and UK, our business will be harmed.â€‹<29Table of ContentsThere is substantial doubt about our ability to continue as a going concern. We will need to raise substantial additional funding to complete the development of ONS-5010/LYTENAVA outside the EU and UK and support our operations until we are able to generate sufficient revenue from the sales of ONS-5010/LYTENAVA in the EU and UK. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.Developing product candidates is an expensive, risky and lengthy process. We have received a marketing authorization from the European Commission and the MHRA for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU and UK, respectively. We are currently advancing ONS-5010/LYTENAVA through additional clinical development and the regulatory approval process in the United States. Our expenses may increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for, ONS-5010/LYTENAVA outside the EU and UK.As of September 30, 2024, our cash and cash equivalents balance was $14.9 million. We do not believe that our existing cash and cash equivalents as of September 30, 2024, together with $1.7 million in net proceeds from the sale of shares of common stock under an at-the-market sales program since September 30, 2024, are sufficient to fund our operations through one year from the Form 10-K filing date. On December 22, 2022, we entered into a Securities Purchase Agreement and issued an unsecured convertible promissory note with a face amount of $31.8 million, or the December 2022 Note, to Streeterville Capital, LLC, or the Lender. In March 2024, the Lender agreed to extend the maturity of the December 2022 Note from April 1, 2024 until July 1, 2025 to provide us time to negotiate the terms to further extend the maturity of the December 2022 Note. See â€œRaising additional capital, including modifications to our existing convertible securities, may cause dilution to our securityholders, restrict our operations or require us to relinquish rights to our technologies and product candidatesâ€ for additional information on the effects of an event of default under the terms of the December 2022 Note. Because our cash and cash equivalents will not be adequate to fund our currently planned operations through at least the next 12 months from the date the consolidated financial statements in this Annual Report on Form 10-K are issued, there is substantial doubt about our ability to continue as a going concern. We will require substantial additional capital to continue to operate as a going concern. Although we continue to pursue discussions with additional potential strategic partners for ONS-5010/LYTENAVA outside of the United States, there is no guarantee that we will be successful in reaching any such agreement, nor that such agreement, if successful, will cover the anticipated commercialization costs for ONS-5010/LYTENAVA. Our operating plan may also change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as through other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. On December 10, 2024, our board of directors approved a reduction of our workforce to reduce operating expenses and preserve capital. On December 13, 2024, we reduced our workforce by five people, or approximately 23% of our existing headcount. At a minimum, all employees affected by the workforce reduction are eligible to receive severance payments and paid COBRA premiums for a specified time period post-termination, subject to execution of a general release of claims against us. We estimate that we will incur approximately $0.3 million in restructuring charges in connection with the workforce reduction, consisting of cash-based expenses related to employee severance and notice period payments, benefits and related costs. While we expect that the majority of the cash payments related to the workforce reduction will be substantially complete by the end of the third calendar quarter of 2025, we may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the workforce reduction. Additionally, we may not achieve the expected benefits of these cost reduction measures and other cost reduction plans on the anticipated timeline, or at all, which could otherwise accelerate our liquidity needs and could force us to further curtail or suspend our operations.Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. We may experience difficulties in accessing the capital markets due to external factors beyond our control, such as volatility in the equity markets for emerging biotechnology companies and general economic and market conditions both in the United States and abroad. For example, 30Table of Contentsour ability to raise additional capital may be adversely impacted by global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, such as has been experienced recently due in part to, among other things, the impacts of inflation, ongoing overseas conflict, and disruptions in access to bank deposits and lending commitments due to bank failure. We cannot be certain that we will be able to obtain financing on terms acceptable to us, or at all. Our failure to obtain adequate and timely funding will adversely affect our business and our ability to develop our technology and products candidates. Moreover, the terms of any financing may negatively impact the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our securities to decline. The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, in order to obtain necessary funding, any of which may harm our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our development programs or the commercialization of ONS-5010/LYTENAVA or any product candidates, if approved. We may also be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could harm our business, financial condition and results of operations.â€‹<Raising additional capital, including modifications to our existing convertible securities, may cause dilution to our securityholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.Until such time, if ever, as we can generate sufficient product revenues, we expect to finance our cash needs through a combination of equity and debt financings, as well as selectively continuing to enter into collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funding. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a securityholder. In December 2022, we issued the December 2022 Note to the Lender. Under the December 2022 Note, upon the occurrence of certain events described therein, including, among others, the Companyâ€™s failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 Note, breaches of representations and warranties in the Securities Purchase Agreement, and the occurrence of certain transactions without the Lenderâ€™s consent (each such event, a Trigger Event), the Lender shall have the right, subject to certain exceptions, to increase the balance of the December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 Note). If a Trigger Event is not cured within ten (10) trading days of written notice thereof from the Lender, it will result in an event of default (such event, an â€œEvent of Defaultâ€). Following an Event of Default, the Lender may accelerate the December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note, â€œConversion Priceâ€ meant, prior to a Major Trigger Event, $40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $40.00 per share (subject to adjustment for stock splits and stock combinations), and (ii) 90% multiplied by the lowest closing bid price of the Companyâ€™s common stock in the three trading days prior to the date on which the conversion notice is delivered. If the Conversion Price is below $3.51 per share, we will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and a 10% participation right in any future debt or equity financings.On January 22, 2024, we entered into an amendment to the December 2022 Note with the Lender, which became effective on April 1, 2024 after satisfaction of certain conditions, including various required stockholder approvals and the closing of the private placement on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025.Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability 31Table of Contentsto take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and may be secured by all or a portion of our assets. If we secure development funds for ONS-5010/LYTENAVA or any future product candidate through entering into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, including for ONS-5010/LYTENAVA, or grant rights to develop and market ONS-5010/LYTENAVA or other product candidates that we would otherwise prefer to develop and market ourselves, terminate product development or future commercialization efforts, including for ONS-5010/LYTENAVA, or to cease operations altogether.â€‹<Risks Related to the Discovery and Development of Our Product CandidatesWe are highly dependent on the success of ONS-5010/LYTENAVA, our only product that has been approved in the EU and UK. If ONS-5010/LYTENAVA does not receive regulatory approval outside the EU and UK, or is not successfully commercialized, our business may be harmed.We currently have one product, ONS-5010/LYTENAVA, that is approved for commercial sale in the EU and UK. We may never be able to obtain regulatory approval for ONS-5010/LYTENAVA outside the EU or UK, commercialize ONS-5010/LYTENAVA in the EU or UK, or develop other marketable products. We expect that a substantial portion of our efforts and expenditures in the foreseeable future will be devoted to the advancement of ONS-5010/LYTENAVA, our only approved product and only product candidate in active development. Â We also expect that we will need to devote significant effort to the commercialization of ONS-5010/LYTENAVA in the EU, UK, and other markets following regulatory approval, if received. We cannot assure you that we will be able to successfully obtain regulatory approval of ONS-5010/LYTENAVA outside of the EU and UK and develop sufficient commercial capabilities for ONS-5010/LYTENAVA if and when necessary. Accordingly, our business currently depends heavily on the successful regulatory approval of ONS-5010/LYTENAVA outside the EU and UK, and commercialization of ONS-5010/LYTENAVA.We cannot be certain that ONS-5010/LYTENAVA will receive regulatory approval outside of the EU or UK, or be successfully commercialized even in the EU or UK, or any other targeted market in which we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market ONS-5010/LYTENAVA in the United States until we receive approval from the FDA, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization.Obtaining approval from the FDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of ONS-5010/LYTENAVA for many reasons, including:â—we may not be able to demonstrate that ONS-5010/LYTENAVA is effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;â—the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;â—the results of our clinical

trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;â—the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;â—the FDA or other relevant regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;32Table of Contentsâ—the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of ONS-5010/LYTENAVA and any future product candidate, or may require that we conduct additional trials;â—the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;â—the FDA or other relevant regulatory authorities may require additional post-marketing studies, which would be costly;â—the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; orâ—the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.There can be no assurance that our BLA or MAAs of ONS-5010/LYTENAVA for wet AMD, or planned future, clinical trials for other retina indications, will ultimately meet the requirements sufficient for us to receive regulatory approval outside of the EU and UK. For example, in May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010/LYTENAVA on August 30, 2022. On August 29, 2023, we received a CRL in which the FDA concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. We received agreement from FDA under the SPA for the NORSE EIGHT trial protocol and completed enrollment in the trial in September 2024. Â In November 2024, we reported that Â ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. There can be no assurance that we will address the deficiencies identified in the CRL to the satisfaction of the FDA.Due to our limited resources and access to capital, we have, and will continue to need to, prioritize development of certain product candidates; and these decisions may prove to have been wrong and may harm our business.Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. We are currently focusing only on one active development program, ONS-5010/LYTENAVA, and are no longer actively developing ONS-3010, ONS-1045 or the other biosimilar product candidates in our pipeline. We currently do not intend to actively develop such biosimilar product candidates. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect to certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the pharmaceutical industry, our business, financial condition and results of operations could be harmed.33Table of ContentsClinical drug development is a lengthy and expensive process and we may encounter substantial delays in our clinical trials or may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.ONS-5010/LYTENAVA, our only product that has been approved for the treatment of wet AMD in the EU and UK, and our only product candidate in active development, required an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL, in advance of our resubmission of a BLA for approval of ONS-5010/LYTENAVA to treat wet AMD in the United States and extensive additional clinical testing before we are prepared to submit an application for regulatory approval for other indications. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we and any collaboration partners must conduct clinical trials to demonstrate the safety and efficacy of the product candidates in humans.We cannot guarantee that any future clinical trials will be conducted as planned or completed on schedule, if at all. For example, enrollment in the NORSE ONE and NORSE TWO studies was delayed from our original expectations. We could experience similar enrollment delays in the remaining NORSE trials (FOUR, FIVE, SIX, and SEVEN) once they are initiated. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:â—inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical trials;â—delays in reaching a consensus with regulatory authorities on study design;â—delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;â—delays in obtaining required IRB approval at each clinical trial site, or positive Ethics Committees opinions;â—imposition of a clinical hold by regulatory authorities, after review of an IND, application or amendment or equivalent filing, or an inspection of our clinical trial operations or trial sites, or as a result of adverse events reported during a clinical trial;â—further delays in recruiting suitable patients to participate in our clinical trials;â—difficulty collaborating with patient groups and investigators;â—failure by our CROs, other third parties or us to adhere to clinical trial requirements;â—failure to perform in accordance with the FDAâ€™s good clinical practice, or GCP, requirements or applicable regulatory guidelines in other countries;â—delays in having subjects complete participation in a study or return for post-treatment follow-up, or subjects dropping out of a study;â—occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;â—changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;â—the cost of clinical trials of our product candidates being greater than we anticipate;34Table of Contentsâ—clinical trials of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical trials or abandon product development programs; andâ—delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.Any inability to successfully complete preclinical studies and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional clinical trials to bridge our modified product candidates to earlier versions.â€‹The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA, EMA and the European Commission or other comparable foreign regulatory authorities.Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. We will be required to demonstrate with substantial evidence through well controlled clinical trials that our product candidates are as safe and effective for use in a specific patient population before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate equivalent safety and efficacy to the satisfaction of the FDA, EMA and European Commission and other comparable foreign regulatory authorities despite having progressed through initial clinical trials. Product candidates that have shown promising results in early clinical trials may still fail in subsequent confirmatory clinical trials. Similarly, the outcome of preclinical testing 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. A number of companies in the pharmaceutical industry, including those with greater resources and experience than we have, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including but not limited to changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and the rate of dropout among clinical trial participants.Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA, EMA or European Commission and other comparable foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change the requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a Phase 3 clinical trial that has the potential to result in FDA or other authoritiesâ€™ approval. For example, in May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010/LYTENAVA on August 30, 2022. On August 29, 2023, we received a CRL in which the FDA concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. Although in January 2024 we reached agreement on a SPA with FDA, this agreement only indicates concurrence with critical trial design concepts; it does not imply that FDA has reviewed, or concurs with, protocol details that do not affect approvability. Moreover, the presence of a SPA agreement does not guarantee that a marketing application will be filed or approved, even if the trial is conducted in accordance with the protocol. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA.35Table of ContentsWe have received marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU and UK. We also intend to seek approval for ONS-5010/LYTENAVA for the treatment of wet AMD outside the EU and UK. Any of the regulatory authorities may approve a product candidate for fewer indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials.â€‹ONS-5010/LYTENAVA and any future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.As with most pharmaceutical products, use of ONS-5010/LYTENAVA and any future product candidates could be associated with side effects or adverse events, which can vary in severity and frequency. Side effects or adverse events associated with the use of ONS-5010/LYTENAVA and any future product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by ONS-5010/LYTENAVA and any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects, toxicity or other safety issues, and could require us to perform additional studies or halt development or sale of ONS-5010/LYTENAVA or any future product candidates or expose us to product liability lawsuits that will harm our business. In such an event, we may be required by regulatory authorities to conduct additional animal or human studies regarding the safety and efficacy of ONS-5010/LYTENAVA or any future product candidates that we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of ONS-5010/LYTENAVA or any future product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory authority in a timely manner, if ever, which could harm our business, prospects and financial condition.Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other related considerations, and as such, any manufacturing process changes we implement prior to or after regulatory approval could impact product safety.Additionally, if one or more of our product candidates receives marketing approval, such as ONS-5010/LYTENAVA, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:â—regulatory authorities may withdraw, vary, or suspend approvals of such product;â—regulatory authorities may require additional warnings on the label;â—we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use, or foreign equivalent strategies;â—we could be sued and held liable for harm caused to patients; andâ—our reputation may suffer.Any of these events could prevent us from achieving or maintaining market acceptance of ONS-5010/LYTENAVA or any other future product candidate that may be approved, and could significantly harm our business, results of operations and prospects.We are required by the FDA, MHRA, EEA authorities and other comparable foreign regulatory authorities to report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may 36Table of Contentsalso fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA, MHRA, the national competent authorities of EEA countries or other foreign regulatory authorities could take action including but not limited to criminal prosecution, the imposition of civil monetary penalties, seizure of our products, withdrawal, variation or suspension of our approvals or delay in approval or clearance of future product candidates.If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates, and our existing insurance coverage may not be sufficient to satisfy any liability that may arise.Drug-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance in the amount of $10.0 million per product candidate and we are required to maintain product liability insurance pursuant to certain of our license agreements. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could negatively impact our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of managementâ€™s attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize ONS-5010/LYTENAVA or any other product candidate and decreased demand for ONS-5010/LYTENAVA or any other product candidate, if approved for commercial sale. Furthermore, we may also not be able to take advantage of limitations on product liability lawsuits that apply to generic drug products, which could increase our exposure to liability for products deemed to be dangerous or defective.â€‹Failure to obtain regulatory approval in any targeted jurisdiction would prevent us from marketing our products to a larger patient population and reduce our commercial opportunities.In order to market our products in Europe, the United States and other jurisdictions, we and any collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We have received a marketing authorization from the European Commission and from the MHRA for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU and UK, respectively. The EU marketing authorization is valid in all EU countries, as well as in Iceland, Liechtenstein and Norway. The time required to obtain approval in other countries may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the European Commission, MHRA or the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We or any collaboration partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products within other European countries, the United States or in other jurisdictions. Failure to obtain these approvals would harm our business, financial condition and results of operations.Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.ONS-5010/LYTENAVA, or any other product candidates we may pursue that are approved, will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including requirements imposed by the EU, other EEA countries and the UK, as well as federal and state requirements in the United States and requirements of other comparable foreign regulatory authorities.Manufacturers and manufacturing facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality

control and manufacturing procedures conform to cGMP regulations. As such, our current and future manufacturing partners will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any non-disclosure agreement, marketing authorization, BLA or marketing authorization application. Accordingly, we and our collaborators and suppliers must 37Table of Contentscontinue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.Any regulatory approvals that we or any collaboration partners receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the productâ€™s approved label. As such, we are not allowed to promote our products for indications or uses for which they do not have approval. We must submit new or supplemental applications and obtain approval for certain changes to the marketing authorizations that have been granted for ONS-5010/LYTENAVA in the EU and UK, or for any other approved products, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal, suspension, or variation of marketing approval.If a regulatory authority discovers previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency or problems with our manufacturing facilities or disagrees with the promotion, marketing or labeling of a product, such regulatory authority may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:â€‹â—issue untitled and warning letters;â—impose civil or criminal penalties;â—suspend, vary or withdraw regulatory approval;â—suspend any of our ongoing clinical trials;â—refuse to approve pending applications or supplements to approved applications submitted by us;â—total or partial suspension of production, distribution or manufacturing;â—impose restrictions on our operations, including closing our manufacturing facilities;â—suspension of licenses; orâ—seize or detain products or require a product recall.Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, suspended or varied, the value of our company and our operating results will be negatively impacted.38Table of ContentsThe development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for ONS-5010/LYTENAVA outside of the EU or UK or in any other indications for which we plan to develop the product, or any future product candidates, on a timely basis or at all.The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to ONS-5010/LYTENAVA, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing approval of biologics in the United States requires the submission of a BLA to the FDA and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls.FDA approval of a BLA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and early clinical trials of ONS-5010/LYTENAVA or any future product candidates may not be predictive of the results of our later-stage clinical trials.Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the biopharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.The FDA could delay, limit or deny approval of a product candidate for many reasons, or request additional information, including because they:â—may not deem our product candidate to be adequately safe and effective;â—may not agree that the data collected from clinical trials are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;â—may determine that adverse events experienced by participants in our clinical trials represents an unacceptable level of risk;â—may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;â—may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;â—may disagree regarding the formulation, labeling and/or the specifications;â—may not approve the manufacturing processes or facilities associated with our product candidate;â—may change approval policies or adopt new regulations; or39Table of Contentsâ—may not accept a submission due to, among other reasons, the content or formatting of the submission.For example, in May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010/LYTENAVA on August 30, 2022. On August 29, 2023, we received a CRL in which the FDA concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled trial clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. In response to FDAâ€™s CRL, we are conducting the NORSE EIGHT clinical trial and completed enrollment in September 2024. In November 2024, we reported that Â ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Generally, public concern regarding the safety of pharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for ONS-5010/LYTENAVA. We may not receive approval from the FDA at the conclusion of its review of the BLA that we intend to resubmit following the completion of NORSE EIGHT, in which case our business, financial condition and results of operations would be further harmed.If we experience additional delays in obtaining approval or if we fail to obtain approval of ONS-5010/LYTENAVA outside the EU and UK, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.â€‹Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before we can initiate clinical trials in the United States in any distinct indication, we must submit the results of preclinical and/or other studies to the FDA along with other information, including information about chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing.Before obtaining marketing approval from the FDA for the sale of a product candidate in any indication, we must conduct extensive clinical studies to demonstrate its safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by CROs, and other third parties for regulatory submissions for ONS-5010/LYTENAVA. While we have or will have agreements governing these third partiesâ€™ services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.The FDA may require us to conduct additional studies for a product candidate before it allows us to initiate clinical trials under any IND, which could lead to additional delays and increase the costs of our development programs. Any such delays in the commencement or completion of our planned or future clinical trials could significantly affect our product development costs. We do not know whether planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:â—the FDA disagreeing as to the design or implementation of our clinical studies;â—obtaining FDA authorizations to commence a trial or reaching a consensus with the FDA on trial design;40Table of Contentsâ—any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;â—obtaining approval from one or more IRBs;â—IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;â—changes to clinical trial protocol;â—clinical sites deviating from trial protocol or dropping out of a trial;â—manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;â—subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;â—subjects choosing an alternative treatment, or participating in competing clinical trials;â—lack of adequate funding to continue the clinical trial;â—subjects experiencing severe or unexpected drug-related adverse effects;â—occurrence of serious adverse events in trials of the same class of agents conducted by other companies;â—selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;â—a facility manufacturing our product candidates or any of their components being ordered by the FDA to temporarily or permanently shut down due to violations of cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;â—any changes to our manufacturing process that may be necessary or desired;â—third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP, or other regulatory requirements;â—third-party contractors not performing data collection or analysis in a timely or accurate manner; orâ—third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or supranational or comparable foreign regulatory authorities.Such authorities may impose such a suspension or termination 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 clinical trial operations 41Table of Contentsor trial site by the FDA or comparable foreign 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 pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or Ethics Committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition and prospects significantly.If we experience delays or difficulties in enrolling patients in our planned clinical trials, our receipt of necessary regulatory approvals of ONS-5010/LYTENAVA outside the EU and UK could be delayed or prevented.We may not be able to initiate or continue our planned clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. Some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as ONS-5010/LYTENAVA or any future product candidates we may develop, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitorsâ€™ product candidates. Patient enrollment is also affected by other factors, including:â—severity of the disease under investigation;â—our ability to recruit clinical trial investigators of appropriate competencies and experience;â—invasive procedures required to obtain evidence of the product candidateâ€™s performance during the clinical trial;â—availability and efficacy of approved medications for the disease under investigation;â—eligibility criteria defined in the protocol for the trial in question;â—the size of the patient population required for analysis of the trialâ€™s primary endpoints;â—perceived risks and benefits;â—efforts to facilitate timely enrollment in clinical trials;â—reluctance of physicians to encourage patient participation in clinical trials;â—the ability to monitor patients adequately during and after treatment;â—our ability to obtain and maintain patient consents; andâ—proximity and availability of clinical trial sites for prospective patients.These factors can be exacerbated by other situations. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.â€‹42Table of ContentsAdverse side effects or other safety risks associated with ONS-5010/LYTENAVA or any future product candidate could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with a product candidate in planned clinical trials. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by a product candidate could result in the delay, suspension or termination of clinical trials by us or the FDA or supranational or comparable foreign regulatory authorities for a number of reasons, or could result in a delay of FDA or comparable foreign regulatory authority approval, similar to our withdrawal of our BLA in May 2022 to provide additional information requested by the FDA. If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of ONS-5010/LYTENAVA or any future product candidate will be harmed and our ability to generate product revenues from this product candidate will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of ONS-5010/LYTENAVA or any future product candidate. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.Moreover, if ONS-5010/LYTENAVA or any future product candidate is associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon or limit its development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations, if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many biologics that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.It is possible that as we test a product candidate in larger, longer and more extensive clinical trials including for additional indications, or as the use of ONS-5010/LYTENAVA or any future product candidate becomes more widespread following regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.In addition, if, following the marketing authorizations of ONS-5010/LYTENAVA in the EU and UK, or if ONS-5010/LYTENAVA receives FDA approval, or if any future product candidate receives marketing approval, and we or others later identify undesirable side effects, a number of potentially significant negative consequences could result, including:â—regulatory authorities may withdraw, suspend, or vary approval of such product;â—we may be required to recall a product or change the way such product is administered to patients;â—regulatory authorities may require additional warnings on the label, such as a â€œblack

boxâ€ warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;â—we may be required to implement a REMS, or create a medication guide outlining the risks of such side effects for distribution to patients, or comparable foreign strategies;â—additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;â—we could be sued and held liable for harm caused to patients;43Table of Contentsâ—such product could become less competitive; andâ—our reputation may suffer.Any of these events could prevent us from achieving or maintaining market acceptance of ONS-5010/LYTENAVA or any future product candidate that may be approved, and could significantly harm our business, results of operations and prospects.Interim, â€œtop-lineâ€ and preliminary results from our clinical trials that we announce or publish from time to time may change as more 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. 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 patient enrollment continues and more patient data become available. 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 previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, top-line or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. 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 and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.Further, 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 development program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, 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 the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.Risks Related to Commercialization of Our Product CandidatesWe face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced or more effective than ours. Other products may be approved and successfully commercialized before ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.We expect to enter highly competitive pharmaceutical markets. Successful competitors in the pharmaceutical markets have demonstrated the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced pharmaceutical companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources. These companies also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates and obtaining FDA and other regulatory approvals of products.44Table of ContentsWe have competitors both in the United States and internationally, including major multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and biotechnology companies we expect to compete with include, for example, Novartis, which currently markets LUCENTIS and BEOVU, Regeneron, with its product EYLEA, Genentech, the marketer of VABYSMO, both Biogen and Coherus with their biosimilar formulations of LUCENTIS and Amgen with their biosimilar formulation of EYLEA, all of which have been approved for use in patients with wet AMD. Furthermore, the cancer drug Avastin, sold by Roche, is used off-label in wet AMD patients although it has not been approved for use in these patients. ONS-5010/LYTENAVA is an approved alternative to the use of off-label Avastin as well as the much more expensive approved therapies in the EU and UK, and is being developed for the same purposes in other markets. In addition, these companies and other, smaller, biotechnology and pharmaceutical companies are also developing new treatments for wet AMD and are at various stages of pre-clinical and clinical development.Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval in countries where we have not yet received approval for ONS-5010/LYTENAVA more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies, and we also compete against such companies for resources from and in securing partnering arrangements with, such large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval in countries where we have not yet received approval for ONS-5010/LYTENAVA, product commercialization and market penetration earlier than we do. Product candidates developed by our competitors may render ONS-5010/LYTENAVA and any of our other potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors.We expect additional companies to seek approval to manufacture and market anti-VEGF therapies for ophthalmic indications. If other anti-VEGF therapies are approved in countries where we have not yet received approval for ONS-5010/LYTENAVA and successfully commercialized before ONS-5010/LYTENAVA, we may never achieve significant market share for this product, our revenue would be reduced and, as a result, our business, prospects and financial condition could be harmed.The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.Even with the requisite approvals from the FDA, European Commission, MHRA and comparable foreign regulatory authorities, the commercial success of ONS-5010/LYTENAVA or any other product candidates we may pursue will depend in part on the medical community, patients and third-party payors accepting ONS-5010/LYTENAVA or our product candidates as medically useful, cost-effective and safe. Even though we expect that ONS-5010/LYTENAVA will be priced responsibly, there is no guarantee that ONS-5010/LYTENAVA or any other product that we bring to the market directly or through a strategic partner will gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of ONS-5010/LYTENAVA or any of our product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:â—the safety and efficacy of the product in clinical trials, and potential advantages over competing treatments;â—the publication of unfavorable safety or efficacy data concerning our product by third-parties;â—the prevalence and severity of any side effects, including any limitations or warnings contained in a productâ€™s approved labeling;â—the clinical indications for which approval is granted;45Table of Contentsâ—recognition and acceptance of our product candidates over our competitorsâ€™ products;â—prevalence of the disease or condition for which the product is approved;â—the cost of treatment, particularly in relation to competing treatments;â—the willingness of the target patient population to try our therapies and of physicians to prescribe these therapies;â—the strength of marketing and distribution support and timing of market introduction of competitive products;â—the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;â—publicity concerning our products or competing products and treatments;â—the extent to which third-party payors provide coverage and adequate reimbursement for ONS-5010/LYTENAVA, or any other product candidates we may pursue that may be approved;â—our ability to maintain compliance with regulatory requirements; andâ—labeling or naming imposed by FDA or other regulatory authorities.Even if ONS-5010/LYTENAVA or any other product candidate we may develop in the future displays an equivalent or more favorable efficacy and safety profile in preclinical and clinical trials, market acceptance of ONS-5010/LYTENAVA or any other product candidate will not be fully known until after it is launched and may be negatively affected by a potential poor safety experience and the track record of other product candidates. Our efforts, or those of any strategic licensing partner, to educate the medical community and third-party payors on the benefits of ONS-5010/LYTENAVA or our other future product candidates may require significant resources, may be under-resourced compared to large well-funded pharmaceutical entities and may never be successful. If ONS-5010/LYTENAVA or any other product candidates we may develop in the future that are approved fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.Although ONS-5010/LYTENAVA is approved in the EU and the UK, off-label repackaging of Avastin at compounding pharmacies may continue, which could have a material adverse effect on our business and financial condition.In the United States, approximately 66.3% of new patient starts are off-label repackaged bevacizumab (ASRS 2022 Membership Survey Presented at ASRS NY 2022), notwithstanding that such use is off-label and requires repackaging at a compounding pharmacy. Although ONS-5010/LYTENAVA is approved for use as a treatment for wet AMD in the EU and the UK, ONS-5010/LYTENAVA has not yet been approved in the United States. Even though ONS-5010/LYTENAVA is approved for use as a treatment for wet AMD in the EU and UK, or even if it is approved in the United States or other countries for the same use, there is no guarantee that we will be effective in reducing the off-label use of Avastin and other drugs in the EU, UK, United States or other major markets where we plan to seek regulatory approval and commercialize ONS-5010/LYTENAVA, directly or through a strategic partner, if approved. If we are not successful in reducing off-label use of Avastin or other drugs with ONS-5010/LYTENAVA, our business and financial condition could be adversely affected. â€‹We currently have no marketing and sales organization. If we are unable to establish and maintain sales and marketing capabilities in jurisdictions for which we choose to retain commercialization rights, we may be unable to generate any revenue.We currently have no internal marketing or sales organization. We have one product, ONS-5010/LYTENAVA, for which we received a marketing authorization in the EU and the UK. We, as a company, have no experience selling and marketing 46Table of Contentsany pharmaceutical products. To successfully commercialize ONS-5010/LYTENAVA or any other products for which we receive approvals, we will need to develop these capabilities, either on our own or with others. If we are not able to secure a strategic licensing partner who will commercialize ONS-5010/LYTENAVA or any other product for which we receive approval, we may need to establish our own sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize ONS-5010/LYTENAVA or any other product candidates that are approved in major markets where we may choose to retain commercialization rights. Doing so will be expensive, difficult and time-consuming. We have entered into a strategic collaboration agreement with Cencora to support the commercial launch of ONS-5010/LYTENAVA globally, with a current focus on the EU, UK, as well as other regions outside of the US, if approved, pursuant to which Cencora would provide third-party logistics services and distribution, as well as medical information and pharmacovigilance services in the EEA and UK, as well as other regions outside the United States. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products. Further, given our lack of prior experience in marketing and selling our products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives and medical support liaisons to adequately support the commercialization of ONS-5010/LYTENAVA or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If our future collaboration partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. If we are unable to establish sales and marketing capabilities for any approved product, whether on our own or through collaborations, including through the strategic collaboration agreement with Cencora, our results of operations will be negatively impacted.â€‹We may need to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of product candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be harmed.Because we have been a pre-commercial biopharmaceutical company, we have found it necessary to enter into alliances with other companies. For example, we entered into a strategic partnership agreement for consulting services for ONS-5010/LYTENAVA, pursuant to which we paid a monthly fee prior to terminating such arrangement. We have also entered into service agreements for clinical trials, and co-development and license agreements for our biosimilar product candidates, and are potentially pursuing strategic partners for ONS-5010/LYTENAVA. In the future, we may also find it necessary to form other alliances or joint ventures with major pharmaceutical companies to jointly develop and/or commercialize the inactive biosimilar product candidates in our pipeline and any other product candidates that we may develop. In such alliances, we would expect our collaboration partners to provide substantial capabilities in regulatory affairs, as well as sales and marketing. We may not be successful in entering into any such alliances, including reaching agreement with a potential partner for ONS-5010/LYTENAVA. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. We may also have disagreements from time to time with our collaboration partners regarding our rights and obligations under such arrangements. If we are not able to successfully resolve disagreements with our contract partners, it could negatively impact our business or reputation. Further, if we are unable to secure or maintain such alliances, we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.In addition to commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. We may not be able to obtain funding on favorable terms from these alliances, and even if so, we may underestimate our development costs, and such fund may not be sufficient to develop a particular product candidate internally or to bring it to market. Failure to bring ONS-5010/LYTENAVA, or any other product candidates we may develop in the future, to market will prevent us from generating sales revenue and this will substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be harmed.47Table of ContentsThe third-party coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.Pricing, coverage and reimbursement of ONS-5010/LYTENAVA, or any other product candidates we may develop in the future that may be approved, may not be adequate to support our commercial infrastructure. Our per-patient prices may not be sufficient to recover our development costs and potentially achieve profitability. The availability of coverage and adequacy of reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments such as ours, if approved. Accordingly, sales of ONS-5010/LYTENAVA or any other of our product candidates that may be approved, will depend substantially, both domestically and abroad, on the extent to which the costs of ONS-5010/LYTENAVA and any of our other product candidates that may be approved, will be paid for by third-party payors such as health maintenance, managed care organizations, pharmacy benefit and similar healthcare management organizations, private health insurers and other third-party payors. If coverage and reimbursement are not available, or are available only at insufficient levels, we may not be able to successfully commercialize ONS-5010/LYTENAVA or any other of our product candidates that may be approved. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if coverage is provided, the approved reimbursement amount may not be adequate to allow us to realize a return on our investment.There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older or those who are disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state to state, covers certain individuals and families who have limited financial means and/or certain disabilities. The Medicare and Medicaid programs increasingly are used as models for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our biosimilar product candidates, if approved. In addition, in the United States, no uniform policy of coverage and reimbursement for biologics exists among third-party payors. Therefore, coverage and reimbursement for biologics can differ significantly from

payor to payor. As a result, the process for seeking favorable coverage determinations often is time-consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.Outside the United States, pharmaceutical businesses are generally subject to extensive governmental price controls and other market regulations. Reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. The EU provides options for EU 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. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer 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. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. â€‹Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.48Table of ContentsWe believe the increasing emphasis on cost-containment initiatives in the EU, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for ONS-5010/LYTENAVA, or any other product candidates we may develop in the future that may be approved. We expect to experience pricing pressures in connection with the sale of ONS-5010/LYTENAVA, or any other product candidates we may develop in the future, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.Off-label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and/or subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.We may only promote or market ONS-5010/LYTENAVA in the EEA and the UK, or any other of our product candidates that may be approved, for their specifically approved indications. We will train our marketing and sales force against promoting ONS-5010/LYTENAVA or any other of our product candidates for uses outside of the approved indications for use, known as â€œoff-label uses.â€ We cannot, however, prevent a physician from using our products off-label, when in the physicianâ€™s independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off-label use of ONS-5010/LYTENAVA or our future product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice, or the DOJ, the Office of Inspector General of the U.S. Department of Health and Human Services, or HHS, state attorneys general, members of the U.S. Congress, and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. In the EEA, the advertising and promotion of medicinal products are subject to both EU and EEA countriesâ€™ laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EEA countries and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the productâ€™s Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries, and investigations, and civil and criminal sanctions by the FDA, DOJ, or comparable foreign authorities. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.The affected populations for ONS-5010/LYTENAVA or any of our other future product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.Our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are estimates based on our 49Table of Contentsknowledge and understanding of these diseases. These estimates may prove to be incorrect and new studies may further reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the EEA, the UK and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain approval for our product candidates, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of our product candidates.The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates included in this Annual Report on Form 10-K or our other filings with the Securities and Exchange Commission, or the SEC, should be viewed with caution. Further, the data and statistical information used in this Annual Report on Form 10-K or our other filings with the SEC, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.If the launch of ONS-5010/LYTENAVA or any of our other future product candidates is further delayed or unsuccessful, or if sales of our marketed products do not meet the levels currently expected, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties or our collaborators.If our product candidates are discontinued or their clinical development is further delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. For example, in May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010/LYTENAVA on August 30, 2022. On August 29, 2023, we received a CRL in which the FDA concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the successful completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. In response to this, we conducted an additional clinical trial, NORSE EIGHT. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. In addition, if we or our future collaborators experience excess inventory, it may be necessary to write down or write off such excess inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results.â€‹50Table of ContentsRisks Related to Our Reliance on Third PartiesWe rely on third parties to conduct our preclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for ONS-5010/LYTENAVA outside the EU and UK, or for any other of our product candidates, or commercialize ONS-5010/LYTENAVA or any other of our product candidates and our business could be harmed.We have relied upon and plan to continue to rely upon CROs to monitor and manage data for our ongoing clinical development programs. We rely on these parties for execution of our preclinical and clinical trials and we can only control certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific requirements and standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, GCP, and GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of EEA countries and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we, any of our CROs, service providers or investigators fail to comply with applicable regulations or GCPs, the data generated in our preclinical and clinical trials may be deemed unreliable and the FDA, MHRA, EMA, European Commission, or comparable foreign regulatory authorities may require us to perform additional preclinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Failure to comply by any of the participating parties or ourselves with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if our CROs or any other participating parties violate supranational, national, federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.If any of our relationships with any of these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.Changing or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can negatively impact our ability to meet our desired clinical development timelines. We may encounter challenges or delays in the future and these delays or challenges may have an adverse effect on our business, financial condition and prospects.Because we may rely on third parties, some of which are or may be sole source vendors for manufacturing and supply of our drug candidates for preclinical and clinical development materials and commercial supplies, our supply may become limited or interrupted or may not be of satisfactory quantity or quality. Our business could be harmed if our current contract manufacturer is unable to manufacture our product candidates at the necessary quantity or quality levels for preclinical, clinical and commercial supply.We currently rely on third-party contract manufacturers for our current and future clinical trial product materials and supplies and do not have the infrastructure or capability internally to manufacture supplies of ONS-5010/LYTENAVA, or any other product candidate, for use in clinical development, and we lack the resources and the capability to manufacture ONS-5010/LYTENAVA or any product candidates on a clinical or commercial scale. If we are unable to manufacture or have manufactured sufficient supplies of ONS-5010/LYTENAVA or any other product candidates, our development 51Table of Contentsefforts would be delayed, which would adversely affect our business and prospects. We have selected FUJIFILM Diosynth Biotechnologies, or FUJIFILM to manufacture and supply us with our product candidates for future clinical development, as well as to establish commercial supplies of ONS-5010/LYTENAVA and our product candidates. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce ONS-5010/LYTENAVA or our product candidates on a timely basis or on commercially viable terms. Establishing additional or replacement vendors, including FUJIFILM, if required, may not be accomplished quickly. Any delays resulting from manufacturing or supply interruptions associated with our reliance on third-party manufacturing and supply partners could impede, delay, limit or prevent our drug development and commercialization efforts. Any significant delay or discontinuation in the supply of a product candidate for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the United States. Our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of ONS-5010/LYTENAVA or any other product candidates that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.We may need to enter into agreements with another third party for contract manufacturing of ONS-5010/LYTENAVA, or any other product candidates that may be approved, in order to produce the quantities necessary to meet anticipated market demand. If we are unable to build and stock ONS-5010/LYTENAVA or any other of our product candidates that may be approved, in sufficient quantities to meet the requirements for the launch of ONS-5010/LYTENAVA or these product candidates or to meet future demand, our revenue and gross margins could be adversely affected. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements for ONS-5010/LYTENAVA or our product candidates or materials used to produce them on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development or market ONS-5010/LYTENAVA or any other of our product candidates that may be approved.â€‹Any adverse developments affecting the manufacture of ONS-5010/LYTENAVA could substantially increase our costs and limit supply for such product candidate.The process of manufacturing our ONS-5010/LYTENAVA and our other monoclonal antibody product candidates is complex, highly regulated and subject to several risks, including but not limited to:â—failure to establish contracts with CMOs, and device vendors where applicable;â—product loss due to contamination,

equipment failure or improper installation or operation of equipment or vendor or operator error;â—infringing intellectual property rights of third parties relating to manufacturing and quality testing;â—failure to achieve or maintain compliance with MHRA, EEA authoritiesâ€™ or FDAâ€™s requirements for acceptance of the applicable manufacturing facilities; and52Table of Contentsâ—labor shortages, natural disasters and power failures.Even minor deviations from normal manufacturing processes for ONS-5010/LYTENAVA or any of our product candidates could result in reduced production yields, product defects and other supply disruptions. In addition, if we require a change in CMO, this will add time along with financial and personnel resources to change manufacturing sites. If microbial, viral or other contaminations are discovered in ONS-5010/LYTENAVA or our product candidates or in our manufacturing facilities, our facilities may need to be closed for an extended period of time to investigate and remedy the contamination.Any adverse developments affecting manufacturing operations for ONS-5010/LYTENAVA or our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of ONS-5010/LYTENAVA or our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for ONS-5010/LYTENAVA or product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.We depend on third parties for the commercialization of ONS-5010/LYTENAVA in the EU and UK, and may depend on third parties for the commercialization of ONS-5010/LYTENAVA in the United States, if approved. Failure to commercialize in the relevant markets could harm our business and operating results.We continue to pursue discussions for the licensing and/or co-development rights to ONS-5010/LYTENAVA outside of the U.S. We may not be successful in reaching agreements with such parties on terms that are as favorable to our company as we would anticipate. We do not have in place any licensing agreements for commercialization of ONS-5010/LYTENAVA and have only licensed ONS-5010/LYTENAVA to our PRC-joint venture, for commercialization in greater China. Our current arrangements are for our inactive biosimilar product candidates, and aside from one U.S. arrangement for ONS-3010, are for smaller ex-U.S. markets where we would not otherwise intend to commercialize our biosimilar product candidates, such as China and India, among others. If any entity with whom we enter into a commercialization arrangement fails to exercise commercially reasonable efforts to market and sell our approved products in their respective licensed jurisdictions or are otherwise ineffective in doing so, our business will be harmed and we may not be able to adequately remedy the harm through negotiation, litigation, arbitration or termination of the license agreements.We have also entered into a strategic relationship with Cencora in preparation for the anticipated commercial launch of ONS-5010/LYTENAVA in the EEA, UK, and in the United States, if approved by the FDA, pursuant to which Cencora would provide comprehensive launch support in the EEA and the UK including pharmacovigilance, regulatory affairs, quality management, market access support, importation, field solutions, third-party logistics services and distribution, andmedical information, as well as other regions outside the United States. If Cencora is unable to provide services pursuant to the strategic relationship, or otherwise breaches the terms of our agreement with them, our commercialization efforts in the EEA and UK could be delayed or adversely impacted, and our business, financial condition and prospects may be adversely effected. â€‹Moreover, any disputes with the third parties on which we rely concerning the adequacy of their commercialization efforts will substantially divert the attention of our senior management from other business activities and will require us to incur substantial legal costs to fund litigation or arbitration proceedings.In the event that any of our license agreements or our strategic relationship with Cencora terminates, we may need to find another partner in those markets to commercialize and in certain instances, manufacture any product candidates. Further, upon any such termination, our contract counterparties may still have the right to commercialize these product candidates in such markets, which may affect our ability to commercialize in the same markets.Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.Because we rely, and continue to expect to rely on third parties to manufacture our current and any future product candidates, and we expect to continue to collaborate with third parties on the development of our current and any future 53Table of Contentsproduct candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, CROs, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitorâ€™s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensorsâ€™ intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitorâ€™s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.We currently engage single source suppliers for clinical trial services and multiple source suppliers for future drug substance manufacturing, fill-finish manufacturing and product testing of ONS-5010/LYTENAVA. The loss of any of these suppliers, or any future single source suppliers, could harm our business.ONS-5010/LYTENAVA is fill-finished by Ajinomoto Bio-Pharma Services, Inc., or Ajinomoto. As such, we are heavily dependent on Ajinomoto for supplying us with sufficient supply of ONS-5010/LYTENAVA. Additionally, we selected FUJIFILM Diosynth Biotechnologies to conduct all future manufacturing of ONS-5010/LYTENAVA bulk drug substance. Although we believe that there are alternate sources for these services, we cannot assure you that identifying and establishing new relationships would not result in significant delay in the development of ONS-5010/LYTENAVA. Additionally, we may not be able to enter into arrangements with alternative vendors on commercially reasonable terms, or at all. A delay in the development of ONS-5010/LYTENAVA or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could negatively impact our business.Risks Related to Intellectual PropertyIf we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.Our commercial success depends in large part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.54Table of ContentsOur research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties.Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We have conducted patent searches for third-party patents with respect to our lead product candidate, and are not aware of third-party patent families with claims that, if valid and enforceable, could be construed to cover such product candidates or their respective methods of manufacture or use. We cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. The existence of any patent with valid and enforceable claims covering one or more of our product candidates could cause substantial delays in our ability to introduce a candidate into the U.S. market if the term of such patent extends beyond our desired product launch date.There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions that do not require publication of patent applications until 18 months after filing. Moreover, we may face claims from non-practicing third-party entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, the scope of patent claims is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the asserted patent claims or that the claims are invalid and/or unenforceable, and we may not be successful.Proving that a patent is invalid or unenforceable is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. In proceedings before courts in the EU, the burden of proving invalidity of a patent also usually rests on the party alleging invalidity. Even if we are successful in litigation, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted, which could harm our business. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial monetary damages. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or are required to seek licenses from third parties, these licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license may obligate us to pay substantial license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property.Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would likely involve substantial litigation expense and would likely be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may, in addition to being blocked from the market, have to pay substantial monetary damages, including treble damages and attorneysâ€™ fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in 55Table of Contentsforeign countries, regarding intellectual property rights with respect to our current or future products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights.Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the EU states (including Switzerland) seeking to extend certain patent protection that, if approved, may interfere with or delay the launch of one or more of our product candidates.The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.So called â€œsubmarineâ€ patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.The term â€œsubmarineâ€ patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from a U.S. application with an effective filing date prior to June 8, 1995 that was not published, publicly known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may be issued to our competitors covering our product candidates and thereby cause significant market entry delay, defeat our ability to market our product candidates or cause us to abandon development and/or commercialization of a product candidate.The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a candidate into the U.S. market.We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products.We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patentâ€™s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline candidates. We may incorrectly determine that our products are not covered by a third party patent. Further, we may conclude that a well-informed court or other tribunal would find the claims of a relevant third-party patent to be invalid based on prior art, enablement, written description, or other ground, and that conclusion may be incorrect, which may negatively impact our ability to market our products or pipeline molecules.Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of a reference product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. We may not identify all relevant patents, or incorrectly determine their expiration dates, which may negatively impact our ability to develop and market our products.56Table of ContentsOur failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, market and commercialize our products.We may become involved in lawsuits to protect or enforce any future patents, which could be expensive, time-consuming and unsuccessful.We have issued patents and when and if we do obtain additional issued patents, we may discover that competitors are infringing these patents. Expensive and time-consuming litigation may be required to enforce our patents. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patentâ€™s claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and

selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.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 any litigation we initiate to enforce our patents. There could also 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, it could have a negative impact on the market price of our securities. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.We employ individuals and retain independent contractors and consultants and members on our board of directors who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us and we are not currently subject to any claims that they have done so, we may in the future be subject 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 personnel, which could adversely impact our business. 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.In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be 57Table of Contentsunsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.If we are unable to obtain and maintain effective patent rights for ONS-5010/LYTENAVA or any future product candidates, we may not be able to prevent competitors from using technologies we consider important in the development and commercialization of ONS-5010/LYTENAVA or any future product candidates, resulting in loss of any potential competitive advantage our patents may have otherwise afforded us.While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. Our ability to enjoy any competitive advantages afforded by our own intellectual property depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. 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. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications.The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions for which legal principles remain unresolved. As a result, the patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patent claims being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business.Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time.Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products from using our proprietary technology. Further, because patent applications in the United States and most other countries are confidential for a period of time, 58Table of Contentstypically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.In addition to our issued patents, we have patent applications in the United States and other jurisdictions, which are currently pending, directed to various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will be issued, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened or infringed by third parties. Any successful actions by third parties to challenge the validity or enforceability of any patents that may be issued to us could deprive us of the ability to prevent others from using the technologies claimed in such issued patents.Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. We are currently experiencing delays in our anticipated timeline for FDA approval of ONS-5010/LYTENAVA due to the FDA requirement to successfully complete an additional adequate and well-controlled trial for ONS-5010/LYTENAVA, which could result in a reduced period of time during which we could market ONS-5010/LYTENAVA under patent protection if ultimately approved by the FDA.â€‹We have filed patent applications directed to our own proprietary formulations and processes for our product candidates when we have believed securing such patents may afford a competitive advantage. For example, the companies that originated Humira and AvastinÂ® (AbbVie and Genentech, respectively) own patents directed to formulations for these products. Rather than wait for the expiration of these formulation patents, we have developed our own proprietary formulations for these products that we believe are not covered by valid claims of third-party patents, including AbbVie or Genentechâ€™s formulation patents; and we have filed patent applications directed to our formulations. We cannot guarantee that our proprietary formulations will avoid infringement of third-party patents. Moreover, because competitors may be able to develop their own proprietary product formulations, it is uncertain whether issuance of any of our pending patent applications directed to formulations of adalimumab (Humira) and bevacizumab (AvastinÂ®) would cover the formulations of any competitors. For example, we are aware that Sandoz is developing biosimilar versions of adalimumab (Humira) and has filed patent applications directed to formulations of adalimumab (Humira). We are also aware that Boehringer is developing a biosimilar version of adalimumab (Humira) and has filed a patent application directed to formulations of adalimumab (Humira). We have patents and patent applications directed to aspects of our downstream manufacturing processes for various biosimilars, including ONS-3010. In contrast to our patent applications directed to formulations of ONS-3010, the proprietary technologies embodied in our process-related patent filings, while directed to inventions we believe may provide us with competitive advantage, were not developed by us to avoid third-party patents. As in the case of our formulation patent filings, it is highly uncertain and we cannot predict whether our patent filings on process enhancements will afford us a competitive advantage against third parties.Obtaining and maintaining our patent protection depends on compliance with various procedural requirements, document submissions, fee payment and other requirements imposed by governmental patent agencies. Our patent protection could be reduced or eliminated for non-compliance with these requirements.The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.59Table of ContentsWe may not be able to protect our intellectual property rights throughout the world.Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our 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 foreign 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, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being approved, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation, including the Leahy-Smith America Invents Act, or the America Invents Act, signed into law on September 16, 2011.As of March 16, 2013, the United States transitioned to a â€œfirst-to-fileâ€ system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third party that files a patent application in the USPTO before us 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. The change to â€œfirst-to-fileâ€ from â€œfirst-to-inventâ€ is one of the changes to the patent laws of the United States resulting from the America Invents Act. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO via procedures including post-grant and inter partes review. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a patent invalidated in a Patent Office post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right. It is not yet clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of 60Table of Contentsour patent applications and the enforcement or defense of any issued patents, all of which could harm our business and financial condition.Further, recent court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I); BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., (Myriad II); and Promega Corp. v. Life Technologies Corp. have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations.In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the United States Congress, the Federal Courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents that we might obtain in the future.If we are unable to maintain effective proprietary rights for ONS-5010/LYTENAVA or our product candidates or any future product candidates, we may not be able to compete effectively in our markets.While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, such as, our employees, consultants, board members, contractors, potential collaborators and financial investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee 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. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the â€œfirst-to-fileâ€ laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes 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 or ownership. If we fail in defending any such claims, in addition to paying monetary damages, 61Table of Contentswe may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could harm our business. 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.If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.We are party to a non-exclusive worldwide commercial license agreements with Selexis, pertaining to clinical testing and sale of its cell line expression technology and we may enter into additional license agreements in the future. Our commercial license agreements with Selexis impose, and we expect that future license agreements will impose, various milestone payments, royalty payments and other obligations on us. If we fail to comply with our obligations under these agreements or if we are subject to a bankruptcy, we may be required to make certain payments to the licensor of our license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates.In the event we breach any of our obligations under these agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:â—the scope of rights granted under the license agreement and other interpretation-related issues;â—the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;â—the sublicensing of patents and other rights;â—our diligence obligations under the license agreement and what activities satisfy those diligence obligations;â—the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; andâ—the priority of invention of patented technology.If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could harm our business.We may not be successful in obtaining or maintaining necessary rights to ONS-5010/LYTENAVA or our product candidates through acquisitions and in-licenses.We currently have rights to certain intellectual property through licenses from third parties, including Selexis, to develop ONS-5010/LYTENAVA/ONS-1045 and ONS-3010. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.62Table of ContentsIf we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.Risks Related to Our Business OperationsOur business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics.Disease outbreaks, epidemics and pandemics, in regions where we have concentrations of clinical trial sites and other business operations, could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and to maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of our product candidates, if at all. For example, patient enrollment and recruitment of NORSE TWO was delayed due to local clinical trial site protocols designed to protect staff and patients from COVID-19 infection. Additionally, general supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. Moreover, the extent to which disease outbreaks, epidemics and pandemics may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. To the extent any future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results of operations and growth prospects, it could also have the effect of heightening many of the other risks and uncertainties described in this â€œRisk Factorsâ€ section.Unfavorable global economic and political conditions could adversely affect our business, financial condition or results of operations.Our results of operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The United States and global economies are facing growing inflation, higher interest rates and potential recession. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the United States dollar would make those clinical trials more costly to operate. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from epidemics, pandemics or ongoing overseas conflict could result in a variety of risks to our business, including weakened demand for ONS-5010/LYTENAVA or any other of our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business. We may not be successful in our efforts to identify, develop or commercialize additional product candidates.Although a substantial amount of our current effort is focused on the potential approval of ONS-5010/LYTENAVA outside the EU and UK, and commercialization of ONS-5010/LYTENAVA, the long-term success of our business also depends upon our ability to identify, develop and commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for clinical development and commercialization for a number of reasons, including but not limited to the following:â—we may not be successful in identifying potential product candidates that pass our strict screening criteria;63Table of Contentsâ—we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost, or at all;â—we may not be able to assemble sufficient resources to acquire or discover additional product candidates;â—our product candidates may not succeed in preclinical or clinical testing;â—competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.If any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would harm our business and could potentially cause us to cease operations.We are highly dependent on the services of our key executives and personnel, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.We are highly dependent on the principal members of our management and scientific and technical staff. The loss of service of any of our management or key scientific and technical staff could harm our business and our prospects in the continued development and commercialization of ONS-5010/LYTENAVA and any future product candidates we may develop. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow our product offering beyond ONS-5010/LYTENAVA.On December 10, 2024, our board of directors approved a reduction of our workforce to reduce operating expenses and preserve capital. On December 13, 2024, we reduced our workforce by five people, or approximately 23% of our existing headcount. Our focus on the development of ONS-5010/LYTENAVA and other potential future drug candidates will require adequate staffing. We may need to hire and retain new employees to execute our future clinical development and manufacturing plans. We cannot provide assurance that we will be able to hire or retain adequate staffing levels to develop our current and potential future drug candidates or to run our operations or to accomplish all of our objectives. We may experience delays or other difficulties effectuating the transition of certain responsibilities that were previously performed by employees impacted by the workforce reduction, which could result in significant disruptions to our business and delays in our development efforts and timelines. In addition, our workforce reduction could yield unanticipated consequences, such as reputational risk, litigation risk and expense, attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and loss of institutional knowledge and expertise. The workforce reduction could also harm our ability to attract and retain qualified personnel who are critical to our operations. In addition, we may need to undertake additional workforce reductions or restructuring activities in the future.We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.Our future performance will also depend, in part, on our ability to successfully integrate new executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of ONS-5010/LYTENAVA or any other of our product candidates, harming future regulatory approvals, sales of ONS-5010/LYTENAVA or any other of our product candidates that may be approved, and our results of operations. Additionally, we do not currently maintain â€œkey personâ€ life insurance on the lives of our executives or any of our employees.64Table of ContentsWe and certain of our officers have been named as defendants in a pending securities class action lawsuit. Certain of our officers and directors have also been named as defendants in a pending shareholder derivative action. These lawsuits, and potential similar or related lawsuits, could result in substantial damages, divert managementâ€™s time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in its outcome.Securities-related class action lawsuits and/or derivative lawsuits have often been brought against companies, including biotechnology and biopharmaceutical companies, that experience volatility in the market price of their securities. This risk is especially relevant for us because we often experience significant stock price volatility in connection with our product development activities.On November 3, 2023, a securities class action lawsuit was filed against us and certain of our officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by us related to our BLA during the period from December 29, 2022 through August 29, 2023. The complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that we and/or our manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time our BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve our BLA, and that our stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneysâ€™ fees. Defendantsâ€™ motion to dismiss is currently pending before the court.On October 10, 2024, certain of the companyâ€™s officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. Â The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the company to violate federal securities laws based on the same alleged misstatements as the securities class action. Â The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. Â The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneysâ€™ fees, and other costs.It is possible that additional lawsuits will be filed, or allegations received from stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. Such lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of such lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible cost to us from this matter, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. Monitoring, initiating and defending against legal actions is time-consuming for our management, is likely to be expensive and may detract from our ability to fully focus our internal resources on our business activities. We could be forced to expend significant resources in the settlement or defense of the pending lawsuits and any potential future lawsuits, and we may not prevail in such lawsuits. Additionally, we may not be successful in having any such lawsuits dismissed or settled within the limits of our insurance coverage.We have not established any reserve for any potential liability relating to the pending lawsuits or any potential future lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests in the pending lawsuits, or in similar or related litigation, could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our business, our stock price, cash flow, results of operations and financial condition.65Table of ContentsHealthcare legislative reform measures and other regulatory reforms may harm our business and results of operations.In the United States, there have been and continue to be a number of legislative initiatives to improve the access to and quality of healthcare, and to contain healthcare costs. For example, in March 2010, the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, imposed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care organizations, added a provision to increase the Medicaid rebate for line extensions or reformulated drugs, established annual fees on manufacturers and importers of certain branded prescription drugs and biologic agents, and promoted a new Medicare Part D coverage gap discount program. The Affordable Care Act also expanded eligibility for Medicaid programs and introduced a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. There have been judicial, Congressional and executive branch challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the â€œindividual mandateâ€ was repealed by Congress. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. For example, on August 16, 2022, President Biden signed the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the â€œdonut holeâ€ under the Medicare Part D program beginning in 2025 by significantly lowering the

beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and any additional healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. Accordingly, we continue to evaluate the potential impact of the Affordable Care Act and its possible repeal or replacement on our business.In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, led to aggregate reductions of Medicare payments to providers up to 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments will stay in effect until 2032 unless additional Congressional action is taken. Additionally, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drugâ€™s average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.In addition, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, In July 2021, the Biden administration released an executive order, â€œPromoting Competition in the American Economy,â€ with multiple provisions aimed at prescription drugs. In response to Bidenâ€™s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated â€œmaximum fair priceâ€ under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in 66Table of Contentsfiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to fifteen additional drugs covered under Part D for negotiation in 2025. HHS has and will continue to issue and update guidance as these programs are implemented. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. On December 7, 2023, the Biden administration also announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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 the Affordable Care Act, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that we receive for any approved product, particularly in light of the U.S. presidential and Congressional elections. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms could result in reduced demand for our product candidates or additional pricing pressures, and may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.In December 2021, Regulation No 2021/2282 on Health Technology Assessment was adopted in the EU. This Regulation, which entered into force in January 2022 will apply from January 2025. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.â€‹In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on 10 April 2024, the Parliament adopted its related position. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.We are subject, directly and indirectly, to foreign, federal, and state healthcare laws and regulations, including fraud and abuse, false claims, physician payment transparency and health information privacy and security laws. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties.Our operations are directly and indirectly through our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject to various foreign, federal, and state fraud and abuse laws, including without limitation, the federal Anti-Kickback Statute, the civil False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our clinical research, proposed sales, marketing, charitable donations and grants, education programs and patient assistance. In addition, we may be subject to 67Table of Contentspatient data privacy and security regulation by both the federal government and the states in which we conduct our business. The healthcare laws that may affect our ability to operate include but are not limited to:â—the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce, reward, or in return for either the referral of an individual for, or the purchase, recommendation, order or furnishing of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;â—federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which can be enforced by private individuals through civil whistleblower or qui tam actions, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented claims for payment from Medicare, Medicaid or other government health programs that are false or fraudulent;â—HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;â—HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which imposes certain requirements, including mandatory contractual terms, relating to the privacy, security and transmission of individually identifiable health information on health plans, certain healthcare providers, and healthcare clearinghouses, known as covered entities, and their business associates that provide services to the covered entity that involve individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information;â—the federal legislation commonly referred to as the Physician Payments Sunshine Act under the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Childrenâ€™s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; andâ—analogous state and foreign laws and regulations, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industryâ€™s voluntary compliance guidelines and the relevant compliance guidance promulgated by the government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state, foreign and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to commit a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.68Table of ContentsIf our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid or comparable foreign programs, individual imprisonment, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources.Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.The international aspects of our business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.We currently have limited international operations of our own and have several international collaborations. 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 or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries;â—additional potentially relevant third-party patent rights;â—complexities and difficulties in obtaining protection and enforcing our intellectual property;â—difficulties in staffing and managing foreign operations by us or our collaboration partners;â—complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems by our collaboration partners;â—limits in our or our collaboration partnersâ€™ 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 products and exposure to foreign currency exchange rate fluctuations;â—natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;â—certain expenses including, among others, expenses for travel, translation and insurance; andâ—regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its anti-bribery provisions, or comparable foreign requirements.If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.Our third-party suppliersâ€™ activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our suppliers are subject to laws and 69Table of Contentsregulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research, development and manufacturing efforts and business operations, and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business. We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including: â—disruption in our relationships with existing strategic partners or suppliers as a result of such a transaction; â—unanticipated liabilities related to acquired companies or joint ventures; â—difficulties integrating acquired personnel, technologies and operations into our existing business; â—retention of key employees; â—diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges; â—increases in our expenses and reductions in our cash available for operations and other uses; and â—possible write-offs or impairment charges relating to acquired businesses.â€‹In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic transactions related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations. Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries. The anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. 70Table of ContentsWe may pursue the development of our product candidates in combination with other approved therapeutics. If the FDA or a comparable foreign regulatory authority revokes approval of any such therapeutic, or if safety, efficacy, manufacturing or supply issues arise with any therapeutic that we use in combination with one of our product candidates in the future, we may be unable to further develop and/or market our product candidate or we may experience significant regulatory delays or supply shortages, and our business could be materially harmed. We may pursue the development of our product candidates in combination with other approved therapeutics, and we may commence clinical trials of our product candidates in combination with other approved therapeutics, in the future. In such a case, we will not have developed or obtained regulatory approval for, nor will we manufacture or sell, any of these approved therapeutics. In addition, the combinations will likely not have been previously tested and may, among other things, fail to demonstrate synergistic activity, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, may exacerbate adverse events

associated with one of our product candidates when used as monotherapy or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy. If the FDA or a comparable foreign regulatory authority revokes its approval of any combination therapeutic, we would not be able to continue clinical development of or market any product candidate in combination with such revoked therapeutic. If safety or efficacy issues were to arise with therapeutics that we seek to combine with, we could experience significant regulatory delays, and the FDA or a comparable foreign regulatory authority could require us to redesign or terminate the applicable clinical trials. In addition, we may need, for supply, data referencing or other purposes, to collaborate or otherwise engage with the companies who market these approved therapeutics. If we are unable to do so on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate or indication, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities.Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data, and comparable foreign regulations. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid or comparable foreign programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.71Table of ContentsOur business activities will be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws.As we expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Â Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, data we collect about trial participants in connection with clinical trials, intellectual property, sensitive third-party data, business plans, transactions, and financial information (collectively, sensitive data).Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). Â For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information.In the past few years, numerous U.S. statesâ€”including California, Virginia, Colorado, Connecticut, and Utahâ€”have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or the CPRA, collectively, the CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA 72Table of Contentsprovides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. Â For example, the European Unionâ€™s General Data Protection Regulation, or the EU GDPR, the United Kingdomâ€™s GDPR, or the UK GDPR, collectively, the GDPR, Brazilâ€™s General Data Protection Law (Lei Geral de ProteÃ§Ã£o de Dados Pessoais, or the LGPD) (Law No. 13,709/2018), and Chinaâ€™s Personal Information Protection Law, or thePIPL impose strict requirements for processing personal data. For example, under the GDPR, in the event of any non-compliance, companies subject to the laws may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. The Swiss Federal Act on Data Protection, or the FADP, also applies to the collection and processing of personal data, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. Our employees and personnel use generative artificial intelligence, or AI, technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Â Governments have passed and are likely to pass additional laws regulating generative AI. Â Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. Â If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Â Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. Â In particular, the European Economic Area, or the EEA, and the United Kingdom, or the UK, have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Â Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Â Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEAâ€™s standard contractual clauses, the UKâ€™s International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. Â If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Â Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Â Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPRâ€™s cross-border data transfer limitations. Â In addition to data privacy and security laws, we are contractually subject to certain industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security. Our efforts to comply with such contractual obligations may not be successful which may lead to claims against us. Â We publish privacy policies, marketing materials, and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. 73Table of ContentsObligations related to data privacy and security (and consumersâ€™ data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Â Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Â Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. Â If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Â Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Â Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations, including our clinical trials. Â If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.In the ordinary course of our business, we and the third parties with whom we work process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats that could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Â Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer â€œhackers,â€ threat actors, â€œhacktivists,â€ organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Â Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. Â During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.Â We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Â Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.Â Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Â Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively 74Table of Contentsaffected by vulnerabilities present in acquired or integrated entitiesâ€™ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data (including data related to our clinical trials) in a variety of contexts, including, without limitation, contract research organizations, employee email, content delivery to customers, and other functions. Â Our ability to monitor these third partiesâ€™ information security practices is limited, and these third parties may not have adequate information security measures in place. Â If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. Â While we may be entitled to damages if these third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our

damages, or we may be unable to recover such award. Â In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third partiesâ€™ infrastructure in our supply chain or our third-party partnersâ€™ supply chains have not been compromised.While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Â We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Â Further, we may experience delays in deploying remedial measures or patches designed to address identified vulnerabilities. Â Vulnerabilities could be exploited and result in a security incident.â€‹Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties with whom we work. Â A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business, including conducting our clinical trials. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Â Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Â Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences. Material security incidents (whether actual or perceived and whether experienced by us or a third party with whom we work) could cause material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data or data related to our clinical trials); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Â Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Â We cannot be sure that our insurance coverage, if any, will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the Company could be leaked, 75Table of Contentsdisclosed, or revealed as a result of or in connection with our employeesâ€™, personnelâ€™s, or vendorsâ€™ use of generative AI technologies.â€‹Risks Related to Ownership of Our SecuritiesThe trading price of our securities is likely to be volatile, and purchasers of our securities could incur substantial losses.The market price of our securities has been and will likely continue to be volatile. The stock market in general and the market in which we operate 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 securities at a profit. The market price of our securities could be subject to wide fluctuations in response to a variety of factors, including but not limited to:â—‹the success of competitive services, products or technologies;â—‹adverse results or delays in preclinical or clinical trials;â—‹any inability to obtain additional funding;â—‹any delay in filing an IND, BLA or other regulatory submission for ONS-5010/LYTENAVA, or any of our product candidates when planned, and any adverse development or perceived adverse development with respect to the applicable regulatory agencyâ€™s review of that IND, BLA or other regulatory submission;â—‹the perception of limited market sizes or pricing for ONS-5010/LYTENAVA or any of our other product candidates;â—‹failure to successfully develop and commercialize ONS-5010/LYTENAVA or any of our other product candidates;â—‹post-marketing safety issues relating to our product candidates generally;â—‹failure to maintain our existing strategic collaborations or enter into new collaborations;â—‹failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;â—‹changes in laws or regulations applicable to our products;â—‹any inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;â—‹adverse regulatory decisions;â—‹introduction of new products, services or technologies by our competitors;â—‹failure to meet or exceed financial projections we may provide to the public;â—‹failure to meet or exceed the financial projections of the investment community;â—‹the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;76Table of Contentsâ—‹announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;â—‹disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;â—‹additions or departures of key scientific or management personnel;â—‹significant lawsuits, including stockholder litigation and litigation filed by us or filed against us pertaining to patent infringement or other violations of intellectual property rights;â—‹the outcomes of any citizens petitions filed by parties seeking to restrict or limit the approval of ONS-5010/LYTENAVA in the EU or UK, or any of our product candidates that may be approved; â—‹if securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock;â—‹changes in the market valuations of similar companies;â—‹general economic, industry or market conditions;â—‹sales of our securities by us or our stockholders in the future;â—‹trading volume of our securities;â—‹issuance of patents to third parties that could prevent our ability to commercialize our product candidates;â—‹the loss of one or more employees constituting our leadership team;â—‹changes in regulatory requirements that could make it more difficult for us to develop our product candidates; andâ—‹the other factors described in this â€œRisk Factorsâ€ section.As further discussed in the Risk Factor above entitled â€œWe and certain of our officers have been named as defendants in a pending securities class action lawsuit. Certain of our officers and directors have also been named as defendants in a pending shareholder derivative action. These lawsuits and potential similar or related lawsuits, could result in substantial damages, divert managementâ€™s time and attention from our business, and have a material adverse effect on our results of operations. These lawsuits, and any other lawsuits to which we are subject, will be costly to defend or pursue and are uncertain in its outcomeâ€, we and two of our officers have been named as defendants a class action lawsuit filed in the United States District Court for the District of New Jersey and certain of our officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. Such lawsuits have often been instituted against companies, including us, whose securities have experienced periods of volatility in market price. The pending lawsuits and any lawsuits brought against us in the future could result in substantial costs, which would hurt our financial condition and results of operations and divert managementâ€™s attention and resources, which could preclude or delay commercialization efforts.In addition, biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance.77Table of ContentsGMS Ventures beneficially owns a significant percentage of our common stock and has the right to designate members to our board of directors and is able to exert significant control over matters subject to stockholder approval, which could prevent new investors from influencing significant corporate decisions.As of September 30, 2024, GMS Ventures owned 5,808,074 shares of common stock and a warrant to acquire an additional Â 3,458,571 shares of common stock. Accordingly, GMS Ventures beneficially owned approximately 33.9% of our common stock as of such date. Under an amended and restated investor rights agreement with GMS Ventures, GMS Ventures also currently has the power to designate members of our board of directors proportionate to the aggregate holdings of GMS Ventures (including any of its affiliates), and two of our ten board members were designated by GMS Ventures. GMS Venturesâ€™ interests may not coincide with the interests of other securityholders. GMS Ventures has the ability to influence our company through its ownership position and its representation on our board of directors, both of which may prevent or discourage unsolicited acquisition proposals or offers for our capital stock that you may believe are in your best interest as one of our securityholders.Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.Our quarterly operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are out of our control and may be difficult to predict, including but not limited to:â—‹our ability to successfully develop, market and sell ONS-5010/LYTENAVA and any other product candidates;â—‹the cost of clinical development for ONS-5010/LYTENAVA and any other product candidates;â—‹the success of competitive products or technologies;â—‹results of clinical trials of our product candidates or those of our competitors;â—‹developments or disputes concerning patent applications, issued patents or other proprietary rights;â—‹the recruitment or departure of key personnel;â—‹the level of expenses related to any of our product candidates or clinical development programs;â—‹the results of our efforts to discover, develop, manufacture, acquire or in-license additional product candidates;â—‹actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;â—‹variations in our financial results or those of companies that are perceived to be similar to us;â—‹market conditions in the pharmaceutical and biotechnology sectors;â—‹general economic, industry and market conditions; andâ—‹the other factors described in this â€œRisk Factorsâ€ section.If our quarterly operating results fall below the expectations of investors or securities analysts, the market price of our securities could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our securities to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.78Table of ContentsIf securities or industry analysts do not publish research, or publish unfavorable research, about our business, the market price of our securities and trading volume could decline.The trading market for our securities depends in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If any analysts who cover us downgrade our securities or change their opinion of our securities, the market price of our securities would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the market price of our securities or trading volume to decline.We are a â€œsmaller reporting companyâ€ and, because we have opted to use the reduced reporting requirements available to us, certain investors may find investing in our securities less attractive.We are a â€œsmaller reporting companyâ€ under the SECâ€™s disclosure rules, meaning that we have either: (i) a public float of less than $250 million; or (ii) annual revenues of less than $100 million during the most recently completed fiscal year; and no public float; or a public float of less than $700 million. As a smaller reporting company, we are permitted to comply with scaled-back disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled-back disclosure in our SEC filings will result in less information about our company being available than for other public companies. If investors consider our common shares less attractive as a result of our election to use the scaled-back disclosure permitted for smaller reporting companies, there may be a less active trading market for our common shares and our share price may be more volatile. We are also a non-accelerated filer under the Exchange Act, and we are not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Therefore, our internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are subject to the auditor attestation requirements. In addition, we cannot predict if investors will find our common shares less attractive because we are not required to comply with the auditor attestation requirements. We cannot predict if investors will find our securities less attractive because we rely on these available exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the market price of our securities may be more volatile.We have and will continue to incur significant costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our operating results.As a public company listed in the United States, we have and will continue to incur significant additional legal, accounting and other expenses. The Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and The Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq, or as a result of stockholder activism, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report, on the effectiveness of our internal control over financial reporting by Section 404 of the Sarbanes-Oxley Act, or Section 404. Our testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 requires us to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group and rely on independent contractors for control monitoring and for the preparation and review of our consolidated financial statements. If we are not able to comply with the requirements of Section 404 in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock 79Table of Contentscould decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of managementâ€™s time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.Further, failure to comply with these laws, regulations and standards might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.Future sales and issuances of our common stock or rights to purchase securities, including pursuant to our equity incentive plans or exercise of warrants, could result in additional dilution of the percentage ownership of our stockholders and could cause the market price of our securities to fall.We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.Pursuant to the 2024 Equity Incentive Plan, or the 2024 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Under the 2024 Plan, the number of shares of our common stock reserved for future issuance as of September 30, 2024 was 4,680,755 shares. In addition, we have reserved shares for issuance under our 2016 Employee Stock Purchase Plan, or the ESPP, which similarly provides for an annual â€œevergreenâ€ increase unless determined otherwise by our board of directors. If our board of directors does not elect to reduce the annual increases in the number of shares available for future grant under the 2024 Plan or the ESPP, our stockholders may experience additional dilution, which could cause the market price of our securities to fall. We also currently have issued and outstanding a number of warrants to purchase an aggregate of 14,207,622 shares of our common stock, at prices ranging from $7.70 to $240.00 per share. Additionally, in December 2022, we issued the December 2022 Note to the Lender. The December 2022 Note is convertible into shares of common stock at the option of the Lender or the Company under certain conditions described in more detail under â€œItem 7. Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€”Liquidity and Capital Resourcesâ€”Description of Indebtedness.â€Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused federal net operating losses, or NOLs, for taxable years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused NOLs expire. Under current law, federal NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of

such federal NOLs is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the federal tax laws.In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an â€œownership change,â€ generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporationâ€™s ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income will be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, 80Table of Contentsthere may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows or results of operations.The enactment of proposed or future tax legislation may adversely impact our financial condition and results of operations. The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions could materially affect our tax obligations. For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenditures over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. In addition, U.S. federal, state and local tax laws are extremely complex and subject to various interpretations. Although we believe that our tax estimates and positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities. If the relevant tax authorities assess additional taxes on us, this could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position.â€‹Our international operations may subject us to greater than anticipated tax liabilities.The amount of taxes we may pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, changes in tax rates, new or revised tax laws or interpretations of existing tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to any future intercompany arrangement or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a â€œpermanent establishmentâ€ under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.We do not intend to pay dividends on our capital stock, and as such any returns will be limited to the value of our securities.We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to securityholders will therefore be limited to the appreciation of their securities.Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our securityholders or remove our current management.Our amended and restated certificate of incorporation, as amended, amended and restated bylaws, as amended and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our charter documents also contain other provisions that could have an anti-takeover effect, such as:â—establishing a classified board of directors so that not all members of our board of directors are elected at one time;81Table of Contentsâ—permitting the board of directors to establish the number of directors and fill any vacancies and newly created directorships;â—providing that directors may only be removed for cause;â—prohibiting cumulative voting for directors;â—requiring super-majority voting to amend some provisions in our amended and restated certificate of incorporation and amended and restated bylaws;â—authorizing the issuance of â€œblank checkâ€ preferred stock that our board of directors could use to implement a stockholder rights plan;â—eliminating the ability of stockholders to call special meetings of stockholders; andâ—prohibiting stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders.These provisions, alone or together, could delay, deter or prevent hostile takeovers and changes in control or changes in our management.In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.Any provision of our amended and restated certificate of incorporation or amended and restated bylaws, each as amended, or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our securityholders to receive a premium for their securities and could also affect the price that some investors are willing to pay for our securities.Our amended and restated certificate of incorporation and our amended and restated bylaws, each as amended, provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholdersâ€™ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.Our amended and restated certificate of incorporation and our amended and restated bylaws, each as amended, provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, each as amended, or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.The choice of forum provision may limit a stockholderâ€™s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation or in our amended and restated bylaws, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business and financial condition.82Table of ContentsSales of substantial amounts of our outstanding common stock in the public market could cause our common stock price to fall. Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate. In addition, in the future, we may issue shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance, including pursuant to any at-the-market agreements, could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.Item 1B. Unresolved Staff CommentsNot applicable.Item 1C. CybersecurityRisk management and strategyWe depend on the functioning, availability and security of our information systems, including financial, data processing, communications and operating systems. Several information systems, such as software applications and cloud platforms, are provided by third parties. Our cybersecurirty risk framework is designed to allow us to identify, assess and manage the cybersecurity risks we face in relation to, our systems and the information we process. As part of our framework, we maintain certain processes defined to assess, identify and manage risks. Â For example, we have an incident management and response process under which we communicate the details of certain threats and incidents to management and the board as may be appropriate; use manual and automated processes that are designed to monitor relevant information systems for vulnerabilities, threats and incidents; manage and take certain actions designed to address incidents that may occur; and take actions designed to remediate certain vulnerabilities identified in relevant enviornements. We employ an array of data security technologies, processes, and methods across our infrastructure designed to protect our systems and sensitive information from unauthorized access. We work with Â information technology consultants who provide advice and expertise on monitoring evolving industry practices. Our assessment and management of material risks from cybersecurity threats are integrated into the Companyâ€™s overall risk management processes. For example, certain management executives, including our Executive VP and Chief Financial Officer evaluates material risks from cybersecurity threats in Â connection with our overall business objectives and reports such evaluations to the audit committee of the board of directors as appropriate, which then evaluates our overall enterprise risks. In addition to the third parties above, we use additional third-party service providers to perform a variety of functions throughout our business, such as enterprise and employee management platforms, labs, contract research organizations, contract manufacturing organizations, and supply chain resources. Depending on the nature of the services provided, the sensitivity of the information systems and data at issue, and the identity of the provider, we take steps designed to address cybersecurity risks that such service providers may present to us, such as conducting diligence into such service providersâ€™ cybersecurity practices and risk profiles.. â€‹For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part I. Item 1A. Risk Factors in this Annual Report on Form 10-K, including If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.â€‹83Table of ContentsGovernanceâ€‹Our cybersecurity risk assessment and management processes are implemented and maintained by certain management, including our Director of Information Technology, who has more than two decades of information technology and information technology leadership experience. Our Director of Information Technology, under the supervision of our Executive VP and Chief Financial Officer, manages and monitors our cybersecurity risk (including that presented by our information technology service providers). Our Director of Information Technology is responsible for informing our Executive VP and Chief Financial Officer of relevant cybersecurity risks including, as relevant, the prevent, detection, mitigation and remediation of cybersecurity incidents. Our Executive VP and Chief Financial Officer has over two decades of management experience, including oversight over information technology and cybersecurity matters.â€‹Our Board of Directors, with the assistance of the Audit Committee, has oversight for the cybersecurity risks facing us and for our processes designed to identify, prioritize, assess, manage, and mitigate those risks. As part of its oversight responsibilities, the Audit Committee receives periodic updates on cybersecurity and information technology matters and related risk exposures (including, as relevant, those stemming from certain cybersecurity incidents) from our Executive VP and Chief Financial Officer.â€‹â€‹Item 2. PropertiesOur headquarters are located in Iselin, New Jersey where we occupy approximately 3,726 square feet of office space under a lease that expires in April 30, 2029. In March 2021, we entered into a three-year term corporate office lease for our former corporate headquarters in Iselin, New Jersey that ended on April 30, 2024.Item 3. Legal ProceedingsOn November 3, 2023, a securities class action lawsuit was filed against us and certain of our officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Exchange Act in connection with allegedly false and misleading statements made by us related to our BLA during the period from August 3, 2021 through August 29, 2023. The complaint alleges, among other things, that we violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that we and/or our manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time our BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve our BLA, and that our stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneysâ€™ fees. Defendantsâ€™ motion to dismiss is currently pending before the court.On October 10, 2024, certain of the companyâ€™s officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. Â The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the company to violate federal securities laws based on the same alleged misstatements as the securities class action. Â The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. Â The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneysâ€™ fees, and other costs.The pending lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and we may not prevail. In addition, we may incur substantial legal fees and costs in connection with such lawsuits. We currently are not able to estimate the possible cost to us from these matters, as the pending lawsuits are currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that we may be required to pay. Such amounts could be material to our financial statements if we do not prevail in the defense of the pending lawsuits and any other related lawsuits, or even if 84Table of Contentswe do prevail. We have not established any reserve for any potential liability relating to the pending lawsuits and any other related lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages.From time to time, we may also become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no additional claims or actions pending against us, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.Item 4. Mine Safety DisclosuresNot applicable.â€‹85Table of ContentsPART IIItem 5. Market for Registrantâ€™s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity SecuritiesMarket InformationOur common stock is traded on The Nasdaq Capital Market under the symbol â€œOTLKâ€.Common StockholdersAs of December 14, 2024, there were approximately 78 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.Dividend PolicyWe have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.Securities Authorized for Issuance Under Equity Compensation PlansThe information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.Recent Sales of Unregistered Equity SecuritiesNone.Issuer Purchases of Equity SecuritiesWe did not repurchase any of our equity securities during fiscal year ended September 30, 2024.Item 6. Reserved.â€‹86Table of ContentsItem 7. Managementâ€™s Discussion and Analysis of Financial Condition and Results of OperationsThe following discussion should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see Item 1A â€œRisk Factorsâ€ in this Annual Report on Form 10-K. See also â€œCautionary Note Regarding Forward-Looking Statements and Industry Data.â€ We caution the reader not to place undue reliance on these forward-looking statements, which reflect managementâ€™s analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Form 10-K.OverviewWe are a biopharmaceutical company working to launch the first ophthalmic formulation of bevacizumab approved by the European Commission in the European Union (EU), the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) and the U.S. Food and Drug Administration (FDA), for use in retinal indications. Our initial goal is to launch directly or with a partner in the EU and UK, and, if approved, to launch directly in the United States as the first and only approved ophthalmic bevacizumab for the treatment of retina conditions, including wet age-related macular degeneration, or wet AMD. Our plans also include seeking approval and launching the product in Japan and other markets. On May 27, 2024, we received a marketing authorization from the European Commission for ONS-5010/LYTENAVA for the treatment of wet AMD. The authorization is valid throughout the European Economic Area, or the EEA, and provides eight years of data exclusivity and 10 years of market exclusivity. On July 8, 2024, we also received marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the UK, followed by a

recommendation by the UK National Institute for Health and Care Excellence (NICE) for LYTENAVAâ„¢ (bevacizumab gamma), as an option for the treatment of wet AMD on December 4, 2024. Outside of the United States, we are currently assessing options to commercialize either directly or through a strategic partner.Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody, or mAb, that inhibits VEGF and associated angiogenic activity. In October 2022 we submitted a Marketing Authorization Application, or MAA, for ONS-5010/LYTENAVA with the European Medicines Agency (EMA). The MAA was submitted as a â€˜full-mixed marketing authorization applicationâ€™ based on Article 8.3 of Directive 2001/83/EC. On March 22, 2024, the EMAâ€™s Committee for Medicinal Products for Human Use, or CHMP issued a positive opinion concerning the authorization of ONS-5010/LYTENAVA (bevacizumab gamma), an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD) in the EU. In May 2024, the European Commission granted the Marketing Authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the EU. The decision applied automatically in all 27 EU Member States, and, within 30 days, also to Iceland, Norway and Liechtenstein. Additionally, in April 2024, we submitted a MAA to the MHRA in the UK seeking approval of ONS-5010/LYTENAVA (bevacizumab gamma) for the treatment of wet AMD. The submission was completed under the new International Recognition Procedure (IRP), which allows the MHRA to rely on an authorization received for the same product from one of MHRAâ€™s specified Reference Regulators (RRs) when considering an application for marketing authorization in the UK. These RRs include a positive opinion by the EMAâ€™s CHMP concerning an application for grant of marketing authorization for the same product in the EU. In July 2024, the MHRA granted marketing authorization for ONS-5010/LYTENAVA for the treatment of wet AMD in the UK. ONS-5010/LYTENAVA is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK.Separately, in March 2022, we submitted a BLA with the FDA for ONS-5010/LYTENAVA, an investigational ophthalmic formulation of bevacizumab, which we have developed to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. In May 2022, we voluntarily withdrew our BLA to provide additional information requested by the FDA. We re-submitted the BLA to the FDA for ONS-5010/LYTENAVA on August 30, 2022, and in October 2022, we received confirmation from the FDA that our BLA had been accepted for filing with a goal date of August 29, 2023 for a review decision by the FDA. On August 29, 2023, we received a Complete Response Letter, or CRL, in which the FDA concluded it could not approve the BLA during this review cycle due to several chemical, manufacturing and control, or CMC, issues, open observations from pre-approval manufacturing inspections, and a lack 87Table of Contentsof substantial evidence. At subsequent Type A meetings with the FDA, we learned that the FDA requires the completion of an additional adequate and well-controlled clinical trial evaluating ONS-5010/LYTENAVA, as well as additional requested CMC data indicated in the CRL to approve ONS-5010/LYTENAVA for use in wet AMD. We agreed to conduct an additional adequate, and well-controlled clinical trial following discussions with the FDA in support of our BLA for ONS-5010/LYTENAVA. In December 2023, we submitted a Special Protocol Assessment, or SPA, to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDAâ€™s requirement for a second adequate and well-controlled clinical trial to support our planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, we received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA. If the NORSE EIGHT trial is successful, it would satisfy the FDAâ€™s requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the CRL. In addition, through a Type A meeting and additional interactions with the FDA, we have identified the approaches needed to resolve the CMC comments in the CRL. We are working to address the open CMC items and have concluded a series of Type C and Type D meetings with the FDA to help to resolve these comments prior to reporting top line results from NORSE EIGHT in the fourth quarter of calendar 2024. We completed enrollment of the NORSE EIGHT trial in September 2024. In November 2024, we reported that ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025.Our BLA and MAA submissions for ONS-5010/LYTENAVA in wet AMD involved three clinical trials, which we refer to as NORSE ONE, NORSE TWO and NORSE THREE. The study design for our clinical program to evaluate ONS-5010/LYTENAVA as an ophthalmic formulation of bevacizumab was reviewed at an end of Phase 2 meeting with the FDA in April 2018, and we filed our investigational new drug application, or IND, with the FDA in the first quarter of calendar 2019. In August 2020, we reported achieving the anticipated safety and efficacy proof-of-concept results from NORSE ONE, a clinical experience study. NORSE TWO was our pivotal Phase 3 clinical trial comparing ONS-5010/LYTENAVA to ranibizumab (LUCENTIS). The topline results reported from NORSE TWO in August 2021 showed that ONS-5010/LYTENAVA met the primary and key secondary endpoints for efficacy with clinically impactful change observed for treated patients. In March 2021, we reported that the results from NORSE THREE showed a positive safety profile for ONS-5010/LYTENAVA.As agreed to with the FDA in the SPA, NORSE EIGHT is a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010/LYTENAVA or 0.5 mg ranibizumab intravitreal injections. Subjects received injections at Day 0 (randomization), Week 4, and Week 8 visits. The primary endpoint is the mean change in BCVA from baseline to week 8. In November 2024, we reported that Â ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010/LYTENAVA. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, we plan to resubmit the BLA application for ONS-5010/LYTENAVA in the first quarter of calendar 2025. If approved, we expect to receive 12 years of regulatory exclusivity in the United States.Additionally, in November 2021, we began enrolling patients in our NORSE SEVEN clinical trial. The study compares the safety of ophthalmic bevacizumab in vials versus pre-filled syringes in subjects diagnosed with a retinal condition that would benefit from treatment with intravitreal injection of bevacizumab, including exudative age-related macular degeneration, DME, or BRVO. Subjects will be treated for three months, and the enrollment of subjects in the arm of the study receiving ONS-5010/LYTENAVA in vials has been completed.We have also received agreement from the FDA on three SPAs for three additional registration clinical trials for our ongoing Phase 3 program for ONS-5010/LYTENAVA. The agreements reached with the FDA on these SPAs cover the 88Table of Contentsprotocols for NORSE FOUR, a registration clinical trial evaluating ONS-5010/LYTENAVA to treat BRVO, and NORSE FIVE and NORSE SIX, two registration clinical trials evaluating ONS-5010/LYTENAVA to treat DME. The timing for initiating these studies has not been determined pending initial FDA approval for wet AMD.Because there are no approved bevacizumab products for the treatment of retinal diseases in the United States and other major markets, we submitted a standard BLA, and are not using the biosimilar drug development pathway that would be required if Avastin were an approved drug for the targeted diseases. If approved in the United States, we believe ONS-5010/LYTENAVA has potential to mitigate risks associated with off-label use of unapproved bevacizumab. In the United States, 66.3% of retina physicians state off-label repackaged bevacizumab is their most commonly used first-line anti-VEGF (ASRS 2022 Membership Survey Presented at ASRS NY 2022).â€‹On December 10, 2024, our board of directors approved a reduction of our workforce to reduce operating expenses and preserve capital. On December 13, 2024, we reduced our workforce by five people, or approximately 23% of our existing headcount. At a minimum, all employees affected by the workforce reduction are eligible to receive severance payments and paid COBRA premiums for a specified time period post-termination, subject to execution of a general release of claims against us. We estimate that we will incur approximately $0.3 million in restructuring charges in connection with the workforce reduction, consisting of cash-based expenses related to employee severance and notice period payments, benefits and related costs. While we expect that the majority of the cash payments related to the workforce reduction will be substantially complete by the end of the third calendar quarter of 2025, we may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the workforce reduction. Additionally, we may not achieve the expected benefits of these cost reduction measures and other cost reduction plans on the anticipated timeline, or at all, which could otherwise accelerate our liquidity needs and could force us to further curtail or suspend our operations.â€‹Going Concern ConsiderationThrough September 30, 2024, we have funded substantially all of our operations withâ€‰$530.9 million in proceeds from the sale and issuance of our equity and debt securities. We have also received $29.0 million pursuant to our collaboration and licensing agreements through such date. Our net loss for the year ended September 30, 2024 was $75.4 million. We also had a net loss of $59.0 million for the year ended September 30, 2023. We have not generated any revenue from product sales. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010/LYTENAVA or any other product candidate we may develop.On May 16, 2023, we entered into an At-the-Market Sales Agreement with BTIG, LLC (â€œBTIGâ€), as sales agent (the â€œBTIG ATM Agreementâ€ or the â€œBTIG ATM Offeringâ€), under which we may issue and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time through BTIG. We incurred financing costs of $0.4 million, which were capitalized and are being reclassified to additional paid in capital on a pro rata basis when we sell common stock under the BTIG ATM Offering. Under the BTIG ATM Agreement, the Company pays BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the BTIG ATM Agreement. The offering of common stock pursuant to the BTIG ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the BTIG ATM Agreement or (ii) termination of the BTIG ATM Agreement in accordance with its terms.In November 2024 and December 2024, we sold 1,000,000 shares of common stock under the BTIG ATM Agreement generated $1.7 million in net proceeds after paying fees to BTIG and other issuance costs of $0.1 million.We evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. We do not believe our current cash resources ofâ€‰$14.9 million as of September 30, 2024, together with $1.7 million in net proceeds from the sale of shares of common stock under the BTIG ATM Offering since September 30, 2024, are sufficient to fund our operations through one year from the Form 10-K filing date. These factors raise substantial doubt about our ability to continue as a going concern. We will need to raise substantial additional capital to fund our planned future operations, receive approval for and commercialize ONS-5010/LYTENAVA, commence and continue clinical trials, or develop other product candidates. We plan to finance our future operations with 89Table of Contentsa combination of proceeds from potential licensing and/or marketing arrangements with pharmaceutical companies, the issuance of equity securities and the issuance of additional debt, potential collaborations and revenues from potential future product sales, if any. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of ONS-5010/LYTENAVA or any other current or future product candidates. If we are unable to secure adequate additional funding, our business, operating results, financial condition and cash flows may be materially and adversely affected. Our consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.Collaboration and License AgreementsFrom time to time, we enter into collaboration and license agreements for the research and development, manufacture and/or commercialization of our products and/or product candidates. These agreements generally provide for non-refundable upfront license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. We have also licensed rights to our legacy biosimilar product candidates (ONS-3010, ONS-1045 and ONS-1050) in other markets.Syntone â€“ Private Placement and PRC Joint VentureIn May 2020, we entered into a stock purchase agreement with Syntone, pursuant to which we sold and issued in a private placement in June 2020, 800,000 shares of our common stock at a purchase price of $20.00 per share, for aggregate gross proceeds of $16.0 million. In connection with the entry into the stock purchase agreement, we entered into a joint venture agreement with Syntoneâ€™s Peopleâ€™s Republic of China, or PRC, based-affiliate, pursuant to which we agreed to form a PRC joint venture that is 80% owned by Syntoneâ€™s PRC-affiliate and 20% owned by us. Upon formation of the PRC joint venture in April 2021, we entered into a royalty-free license with the PRC joint venture for the development, commercialization and manufacture of ONS-5010/LYTENAVA in the greater China market, which includes Hong Kong, Taiwan and Macau.Selexis SAIn October 2011, we entered into a research license agreement with Selexis whereby we acquired a non-exclusive license to conduct research internally or in collaboration with third parties to develop recombinant proteins from cell lines created in mammalian cells using the Selexis expression technology, or the Selexis Technology. See Note 8 in the Notes to Consolidated Financial Statements in this Annual Report on Form 10-K for additional detail. Components of Our Results of OperationsReverse stock splitEffective on March 14, 2024, we amended our amended and restated certificate of incorporation to implement a one-for-twenty reverse stock split of our common stock. The disclosure of our results of operations reflect the reverse stock split for all periods presented.Research and Development ExpensesResearch and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:â—expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;â—expenses incurred by us directly, as well as under agreements with contract manufacturing organizations, or CMOs, for manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;â—outsourced professional scientific development services;90Table of Contentsâ—employee-related expenses, which include salaries, benefits and stock-based compensation;â—payments made under a third-party assignment agreement, under which we acquired intellectual property;â—expenses relating to regulatory activities, including filing fees paid to regulatory agencies;â—laboratory materials and supplies used to support our research activities; andâ—allocated expenses, utilities and other facility-related costs.â€‹The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our other product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:â—the number of clinical sites included in the trials;â—the length of time required to enroll suitable patients;â—the number of patients that ultimately participate in the trials;â—the number of doses patients receive;â—the duration of patient follow-up;â—the results of our clinical trials;â—the establishment of commercial manufacturing capabilities;â—the receipt of marketing approvals; andâ—the commercialization of product candidates.â€‹Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. We may never succeed in achieving regulatory approval for any of our biosimilar product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Full product commercialization will take several years and millions of dollars in additional costs.Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, complexity and duration of later-stage clinical trials.General and Administrative ExpensesGeneral and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for business development, legal, auditing and tax services and insurance costs.We anticipate that our general and administrative expenses will increase if and when we believe a regulatory approval of a product candidate appears likely, and we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, particularly as it relates to the sales and marketing of our product.91Table of ContentsLoss on equity method investmentLoss on equity method investment represents our proportionate share for the period of the net loss of our investee to which the equity method of accounting is applied. We account for equity investments where we own a non-controlling interest, but have the ability to exercise significant influence, under the equity method of accounting.Interest incomeInterest income is earned from short term investments primarily money market investments.Interest ExpenseInterest expense consists of cash paid and non-cash interest expense related to our December 2022 Note. The interest expense was associated with the fees incurred for extending the debt and original issue discount and debt issuance costs that were written off upon election to fair value and accounted for as interest.Loss on Extinguishment of DebtWe recognized a $0.6 million loss on extinguishment related to the prepayment and cancellation our November 2021 Note (as defined below) during the year ended September 30, 2023 that was accounted for as an extinguishment.Change in Fair Value of Promissory Notes The change in fair value relates to convertible promissory notes that we elected to account for at fair value. As permitted under ASC 825, we elected the fair value option to account for our convertible promissory notes. We recorded the convertible promissory note at fair value with changes in fair value recorded in the

consolidated statements of operations.Warrant Related ExpensesThe warrant related expense relates to the excess of the fair value of the warrants upon issuance over the proceeds of the private placements that closed on March 18, 2024 and April 15, 2024. Change in Fair Value of Warrant LiabilityWe issued warrants to purchase our common stock in conjunction with convertible senior secured notes issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017, which are classified as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations as other (income) expense.Income TaxesSince inception, we have not recorded any U.S. federal or state income tax benefits (excluding the sale of New Jersey state NOLs and research and development, or R&D, tax credits) for the net losses we have incurred in each year or on our earned R&D tax credits, due to our uncertainty of realizing a benefit from those items. As of September 30, 2024, we had federal and state NOL carryforwards of $406.7 million and $242.5 million, respectively, that will begin to expire in 2030 and 2039, respectively. As of September 30, 2024, we had federal foreign tax credit carryforwards of $0.3 million available to reduce future tax liabilities, which begin to expire starting in 2023. As of September 30, 2024, we also had federal and state R&D tax credit carryforwards of $13.0 million and $0.8 million, respectively, that will begin to expire in 2032 and 2033, respectively.In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an â€œownership changeâ€ is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in the past. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or 92Table of Contentsafter our Initial Public Offering, or IPO, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.Results of OperationsComparison of Years Ended September 30, 2024 and 2023â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹â€‹â€‹â€‹Â Â Â Â 2024Â Â Â Â 2023Â Â Â Â ChangeOperating expenses:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Research and developmentâ€‹$ 41,763,047â€‹$ 26,452,942â€‹$ 15,310,105General and administrativeâ€‹â€‹ 29,940,188â€‹â€‹ 26,673,440â€‹â€‹ 3,266,748Loss from operationsâ€‹â€‹ (71,703,235)â€‹â€‹ (53,126,382)â€‹â€‹ (18,576,853)â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Loss on equity method investmentâ€‹â€‹ 100,742â€‹â€‹ 10,998â€‹â€‹ 89,744Interest income â€‹â€‹ (906,150)â€‹â€‹ (971,480)â€‹â€‹ 65,330Interest expenseâ€‹â€‹ 3,156,964â€‹â€‹ 2,531,228â€‹â€‹ 625,736Loss on extinguishment of debtâ€‹â€‹ â€"â€‹â€‹ 577,659â€‹â€‹ (577,659)Change in fair value of promissory notesâ€‹â€‹ 2,457,153â€‹â€‹ 3,756,000â€‹â€‹ (1,298,847)Warrant related expensesâ€‹â€‹ 37,490,012â€‹â€‹ â€"â€‹â€‹ 37,490,012Change in fair value of warrant liabilityâ€‹â€‹ (38,638,042)â€‹â€‹ (50,919)â€‹â€‹ (38,587,123)Loss before income taxesâ€‹â€‹ (75,363,914)â€‹â€‹ (58,979,868)â€‹â€‹ (16,384,046)Income tax expenseâ€‹â€‹ 2,800â€‹â€‹ 2,800â€‹â€‹ â€"Net lossâ€‹$ (75,366,714)â€‹$ (58,982,668)â€‹$ (16,384,046)â€‹Research and Development ExpensesThe following table summarizes our research and development expenses by functional area for the years ended September 30, 2024 and 2023:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â Â 2023ONS-5010/LYTENAVA developmentâ€‹$ 37,355,884â€‹$ 28,718,140Compensation and related benefitsâ€‹â€‹ 2,507,635â€‹â€‹ 2,126,772Stock-based compensationâ€‹â€‹ 800,956â€‹â€‹ 986,598Other research and developmentâ€‹â€‹ 1,098,572â€‹â€‹ (5,378,568)Total research and development expensesâ€‹$ 41,763,047â€‹$ 26,452,942â€‹Research and development expenses for the year ended September 30, 2024 increased by $15.3 million compared to the year ended September 30, 2023. The increase was primarily due to an $8.6 million rise in development costs associated with ONS-5010/LYTENAVA related to the commencement and subsequent completion of enrollment in the NORSE EIGHT clinical trial, combined with the effects of a $6.2 million refund for BLA submission fees from the FDA received in the prior period.93Table of ContentsGeneral and Administrative ExpensesThe following table summarizes our general and administrative expenses by type for the years ended September 30, 2024 and 2023:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â Â 2023Professional feesâ€‹$ 9,866,128â€‹$ 14,522,528Compensation and related benefitsâ€‹â€‹ 6,301,200â€‹â€‹ 4,366,447Stock-based compensationâ€‹â€‹ 4,584,168â€‹â€‹ 4,560,421Europe prelaunch expensesâ€‹â€‹ 5,010,687â€‹â€‹ â€"Facilities, fees and other related costsâ€‹â€‹ 4,178,005â€‹â€‹ 3,224,044Total general and administrative expensesâ€‹$ 29,940,188â€‹$ 26,673,440â€‹General and administrative expenses for the year ended September 30, 2024 increased by $3.3 million compared to the year ended September 30, 2023. During the year ending September 30, 2024, we incurred pre-launch expenses in Europe amounting to $5.0 million, along with a $1.9 million increase in compensation and benefits primarily attributed to severance-related costs and adjustments in headcount. These increases were offset by a $4.7 million decrease in professional fees, which resulted from the discontinuation of U.S. commercial launch activities following the receipt of the CRL in August 2023.Loss on Equity Method InvestmentLoss on equity method investment represents our share of the loss from Beijing Syntone Biopharma Ltd, or Syntone JV.Interest IncomeInterest income for the year ended September 30, 2024 and 2023 was earned from short term investments, primarily consisting of money market investments.Interest ExpenseInterest expense for the year ended September 30, 2024 increased by $0.6 million compared to prior year. This increase was primarily attributable to convertible promissory note maturity extension fees of $3.2 million associated with the December 2022 Note incurred during the year, in contrast to $2.5 million incurred in the prior year primarily related to the recognition of the original issue discount as interest expense on the December 2022 Note, as result of our adoption the fair value option for accounting purposes.Loss on Extinguishment of DebtWe recognized a $0.6 million loss on extinguishment related to the prepayment and cancellation of our November 2021 Note (as defined below) during the year ended September 30, 2023 that was accounted for as an extinguishment. Change in Fair Value of Promissory NotesThe change in fair value relates to the convertible promissory notes that we elected to account for at fair value. As permitted under ASC 825, we elected the fair value option to account for our convertible promissory notes. We record the convertible promissory notes at fair value with changes in fair value recorded in the consolidated statements of operations.Warrant Related ExpensesDuring the year ended September 30, 2024, we recognized charges associated with warrants issued during the period, which were categorized as liabilities. The warrant related charges amounted to the difference between the fair value of the warrants and the net proceeds received from private placements that closed on March 18, 2024 and April 15, 2024.94Table of ContentsChange in Fair Value of Warrant LiabilityWe recognized income related to the decrease in the fair value of our common stock warrant liability in both fiscal years 2024 and 2023. This income was attributed to a decline in the price of our common stock during those periods. In fiscal year 2024, we recorded income of $38.6 million, compared to $0.1 million in fiscal year 2023. We issued warrants to purchase our common stock in conjunction with convertible senior secured notes issued pursuant to a certain Note and Warrant Purchase Agreement dated December 22, 2017. Additionally, we issued warrants in connection with private placements that closed on March 18, 2024 and April 15, 2024. These warrants are categorized as liabilities and recorded at fair value. The warrants are subject to re-measurement at each balance sheet date, and we recognize any change in fair value in our statements of operations. The gain recorded during the period was primarily due to the reduction in our stock price per share of common stock during the year.Liquidity and Capital ResourcesWe have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations. Through September 30, 2024, we have funded substantially all of our operations with $530.9 million in net proceeds from the sale and issuance of our equity securities, debt securities and borrowings under debt facilities. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010/LYTENAVA or any other product candidate we may develop. We will need substantial additional financing to fund our operations and to commercially launch ONS-5010/LYTENAVA or any other product candidate we may develop. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include but are not limited to payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, private placements and/or public offerings of equity and/or debt securities. Alternatively, we will be required to, among other things, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.On November 16, 2021, we received $10.0 million in net proceeds from the issuance of an unsecured promissory note (the â€œNovember 2021 Noteâ€), with a face amount of $10.2 million. The November 2021 Note bore interest at a rate of 9.5% per annum, was due to mature January 1, 2023 and included an original issue discount of $0.2 million. We could prepay all or a portion of the note at any time by paying 105% of the outstanding balance elected for prepayment. On December 28, 2022, we prepaid the November 2021 Note in full by paying 105% of the outstanding balance. The total payment was $11.9 million, which included interest of $1.2 million and a prepayment fee of $0.6 million.During the year ended September 30, 2023, we sold 44,769 shares of common stock under our prior at-the-market offering program for $1.1 million in net proceeds, and the fees paid to the sales agent were immaterial. On May 16, 2023, we entered into the BTIG ATM Agreement, under which we may issue and sell shares of common stock having an aggregate offering price of up to $100.0 million from time to time through BTIG. Under the BTIG ATM Agreement, we pay BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the BTIG ATM Agreement. The offering of common stock pursuant to the BTIG ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the BTIG ATM Agreement or (ii) termination of the BTIG ATM Agreement in accordance with its terms. No shares of common stock were sold under the BTIG ATM Offering during the year ended September 30, 2024. During the year ended September 30, 2023, we sold 178,911 shares of common stock pursuant to the BTIG ATM Offering, generating $6.1 million in net proceeds after we paid fees to BTIG of $0.2 million.In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures, our largest stockholder, we issued 1,423,041 shares of common stock at a purchase price per share of $17.568 for $23.2 million in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 711,520 shares of common stock in the registered direct equity offering. In connection with the registered direct equity offering, we issued to M.S. Howells & Co., as placement agent for certain accredited investors in the offering, 95Table of Contentswarrants to purchase up to an aggregate of 25,787 shares of common stock, which will be exercisable commencing on the one-year anniversary of the closing of the offering at an exercise price of $21.00 per share, which warrants have a three-year term.On December 22, 2022, we entered into a Securities Purchase Agreement and issued an unsecured convertible promissory note with a face amount of $31.8 million, or the December 2022 Note, to Streeterville Capital, LLC, or the Lender, the holder of our November 2021 Note. The December 2022 Note has an original issue discount of $1.8 million. A portion of the proceeds from the December 2022 Note were used to repay in full the remaining outstanding principal and accrued interest on the November 2021 Note, which was cancelled upon repayment. We received net proceeds of $18.1 million upon the closing on December 28, 2022, after deducting the Lenderâ€™s transaction costs in connection with the issuance and November 2021 Note repayment. In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. The Company incurred a $475,000 extension fee. The December 2022 Note bore interest at 9.5% per annum through April 1, 2024. On January 22, 2024, the Company entered into an amendment to the December 2022 Note (the â€œJanuary 2024 Note Amendmentâ€) with the Lender, which became effective on April 1, 2024 after satisfaction of certain closing conditions, including various required stockholder approvals and the closing of the private placement that closed on March 18, 2024. Â The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of $2.7 million (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. Under the January 2024 Note Amendment, the initial conversion price with respect to $15.0 million in aggregate principal amount of the December 2022 Note was changed to $7.00, the price per share in the private placement that closed on March 18, 2024 and the remaining aggregate principal amount has a conversion price of $40.00 per share. Effective April 1 2024, the December 2022 Note bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least $3.0 million of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the December 2022 Note) and continuing until the December 2022 Note is repaid in full. The December 2022 Note contains customary covenants, including a restriction on our ability to pledge certain ofour assets, subject to certain exceptions, without the Lenderâ€™s consent. The principal amount and conversion price of the December 2022 Note are subject to adjustment upon certain triggering events. See â€œDescription of Indebtednessâ€ and Note 7 in the Notes to Consolidated Financial Statements in this Annual Report on Form 10-K for additional detail.During the year ended September 30, 2024, an aggregate of principal and accrued interest totaling $11.3 million of the December 2022 Note was converted into 1,607,093 shares of our common stock.In March 2024, in a private placement pursuant to a securities purchase agreement entered into in January 2024 with certain institutional and accredited investors, including GMS Ventures, our largest stockholder, we issued an aggregate of 8,571,423 shares of common stock and warrants to purchase an aggregate of 12,857,133 shares of common stock at a purchase price per share of $7.00 per share and accompanying warrant to purchase one and one-half shares of common stock for $55.5 million in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 2,305,714 shares of common stock and warrants to purchase an aggregate of 3,458,571 shares of common stock in the private placement. The warrants have an exercise price of $7.70 per share of common stock and will expire on March 18, 2029.On April 15, 2024, in a private placement with Syntone Ventures, LLC pursuant to a securities purchase agreement entered into in January 2024, we issued 714,286 shares of common stock and accompanying warrants to purchase 1,071,429 shares of common stock for $4.8 million in gross proceeds on substantially the same terms as those in the private placement closed in March 2024. The warrants have an exercise price of $7.70 per share of common stock and will expire on April 15, 2029.In November 2024 and December 2024, we sold 1,000,000 shares of common stock under the BTIG ATM Agreement generated $1.7 million in net proceeds after paying fees to BTIG and other issuance costs of $0.1 million.We evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. As of September 30, 2024, we had an accumulated deficit ofâ€‰$543.3 million and $31.4 million of principal, accrued interest and exit fees due on the December 2022 Note. We do not believe our current 96Table of Contentscash resources of $14.9 million, together with $1.7 million in net proceeds from the sale of shares of common stock under the BTIG ATM Offering since September 30, 2024, are sufficient to fund our operations through one year from the Form 10-K filing date as a result of the costs associated with the NORSE EIGHT clinical trial and the July 1, 2025 maturity date of the December 2022 Note, as amended in January 2024. These factors raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of ONS-5010/LYTENAVA or any other product candidate we may develop. We will need substantial additional financing to fund our operations and to commercially develop ONS-5010/LYTENAVA or any other product candidate we may develop. Management is currently evaluating various strategic opportunities to obtain the required funding for future operations. These strategies may include but are not limited to payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, private placements and/or public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful. Alternatively, we will be required to, among other things, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.Our future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above, (ii) our ability to complete revenue-generating partnerships with pharmaceutical companies, (iii) the success of our research and development, (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately, (v) regulatory approval and market acceptance of our proposed future products.While we expect that the majority of the cash payments related to the workforce reduction will be substantially complete by the third calendar quarter of 2025, we may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the workforce reduction. Additionally, we may not achieve the expected benefits of these cost reduction measures and other cost reduction plans on the anticipated timeline, or at all, which could otherwise accelerate our liquidity needs and could force us to further curtail or suspend our operations.Cash FlowsThe following table summarizes our cash flows for each of the years presented:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â Â 2023Net cash used in operating activitiesâ€‹$ (68,793,858)â€‹$ (42,973,398)Net cash provided by financing activitiesâ€‹â€‹ 60,329,414â€‹â€‹ 48,968,568Net (decrease) increase in cash and cash equivalentsâ€‹$(8,464,444)â€‹$5,995,170 â€‹Operating ActivitiesDuring the

year ended September 30, 2024, we used $68.8 million of cash in operating activities resulting primarily from our net loss of $75.4 million. This use of cash was partially offset by $9.6 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of promissory notes, warrant related expense, change in fair value of warrant liability, loss on equity method investment and depreciation and amortization expense. The net cash outflow of $3.0 million from changes in our operating assets and liabilities was primarily due to an increase in prepaid expenses of $4.9 million for timing of payments associated with ONS-5010/LYTENAVA development costs relating to clinical trial and drug development costs partially offset by an increase in accounts payable and accrued expenses of $1.9 million due to professional fees associated with our EU launch activities. During the year ended September 30, 2023, we used $43.0 million of cash in operating activities resulting primarily from our net loss of $59.0 million. This use of cash was partially offset by $12.4 million of non-cash items such as stock-based compensation, non-cash interest expense, change in fair value of promissory notes, change in fair value of warrant liability, 97Table of Contentsloss on extinguishment of debt, loss on equity method investment and depreciation and amortization expense. We also paid interest on debt of $1.2 million during the period. The net cash inflow of $4.8 million from changes in our operating assets and liabilities was primarily due to a net increase in accounts payable and accrued expenses of $2.4 million and a decrease in prepaid expenses of $2.6 million related to timing of payments associated with ONS-5010/LYTENAVA development costs, partially offset by an increase in other assets of $0.2 million.Financing ActivitiesDuring the year ended September 30, 2024, net cash provided by financing activities was $60.3 million, primarily attributable to $60.3 million in net proceeds from private placements in March 2024 and April 2024 of an aggregate of Â 9,285,709 shares of our common stock and warrants to purchase an aggregate of 13,928,562 shares of our common stock.During the year ended September 30, 2023, net cash provided by financing activities was $49.0 million, primarily attributable to $23.2 million in net proceeds from a registered direct equity offering in December 2022 of an aggregate of 1,423,041 shares of our common stock, $7.2 million in net proceeds from the sale of common stock under our prior at-the-market offering program and BTIG ATM Offering and $30.0 million in net proceeds from the issuance of the December 2022 Note with a face amount of $31.8 million in December 2022. We also made $10.2 million in debt and finance lease obligation payments and a $0.8 million payment of financing costs. Description of IndebtednessThe December 2022 Note contains customary covenants, including a restriction on the Companyâ€™s ability to pledge certain of the Companyâ€™s assets, subject to certain exceptions, without the Lenderâ€™s consent. Since April 1, 2023, the Lender has the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and Conversion Price of the December 2022 Note were subject to adjustment upon certain triggering events. In addition, the Company has the right to convert all or any portion of the outstanding balance under the December 2022 Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $50.00 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Payments may be made by the Company (i) in cash, (ii) in shares of common stock, with the number of shares being equal to the portion of the applicable payment amount divided by the Conversion Price (as defined below), or (iii) a combination of cash and shares of common stock. Any payments made by the Company in cash, including prepayments or repayment at maturity, will be subject to an additional fee of 7.5%. Upon the occurrence of certain events described in the December 2022 Note, including, among others, the Companyâ€™s failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 Note, breaches of representations and warranties in the Securities Purchase Agreement, and the occurrence of certain transactions without the Lenderâ€™s consent (each such event, a â€œTrigger Eventâ€), the Lender shall have the right, subject to certain exceptions, to increase the balance of the December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 Note). If a Trigger Event is not cured within ten (10) trading days of written notice thereof from the Lender, it will result in an event of default (such event, an â€œEvent of Defaultâ€). Following an Event of Default, the Lender may accelerate the December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note, â€œConversion Priceâ€ meant, prior to a Major Trigger Event, $40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $40.00 per share (subject to adjustment for stock splits and stock combinations), and (ii) 90% multiplied by the lowest closing bid price of the Companyâ€™s common stock in the three trading days prior to the date on which the conversion notice is delivered. The maturity date of the December 2022 Note was extended from January 1, 2024 to April 1, 2024 in December 2023. On January 22, 2024, the Company entered into the January 2024 Note Amendment with the Lender, which became effective on April 1, 2024 after satisfaction of certain closing conditions, including various required stockholder approvals and the closing of the private placement that closed on March 18, 2024. Â The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of $2.7 million (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. Under the January 2024 Note Amendment, the initial 98Table of Contentsconversion price with respect to $15.0 million in aggregate principal amount of the December 2022 Note was changed to $7.00, the price per share in the private placement that closed on March 18, 2024 and the remaining aggregate principal amount is converted at a price ofhas a conversion price of $40.00 per share. Effective April 1 2024, the December 2022 Note bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least $3.0 million of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the December 2022 Note) and continuing until the December 2022 Note is repaid in full. If the Conversion Price is below $3.51 per share, the Company will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and a 10% participation right in any future debt or equity financings.Funding RequirementsWe plan to focus in the near term on supporting the review of our BLA submission for ONS-5010/LYTENAVA with the FDA and to prepare for the potential launch of ONS-5010/LYTENAVA to support the generation of commercial revenues. We anticipate we will incur net losses and negative cash flow from operations for the foreseeable future. We may not be able to initiate commercialization of ONS-5010/LYTENAVA if, among other things, the FDA does not approve our BLA when we expect, or at all, or if we are not able to secure sufficient funding of our expected post-launch commercial costs.Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, manufacturing and facility costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support the marketing and development of our lead product candidate and any other product candidates we may choose to pursue.We do not believe our existing cash and cash equivalents of $14.9 million as of September 30, 2024, together with $1.7 million in net proceeds from the sale of shares of common stock under the BTIG ATM Offering since September 30, 2024, are sufficient to fund our operations through one year from the Form 10-K filing date. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We will need to raise substantial additional capital in order to complete our planned ONS-5010/LYTENAVA development program. We plan to finance our future operations with a combination of proceeds from potential strategic collaborations, sale of the development and commercial rights to our drug product candidates, the issuance of equity securities, the issuance of additional debt, and revenues from potential future product sales, if any. If we raise additional capital through the sale of equity or convertible debt securities, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Further, due to current market volatility, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. There are no assurances that we will be successful in obtaining an adequate level of financing for the commercialization of ONS-5010/LYTENAVA or the development of any other current or future product candidates. Alternatively, we will be required to, among other things, modify our clinical trial plans for ONS-5010/LYTENAVA in additional indications, make reductions in our workforce, scale back our plans and place certain activities on hold, discontinue our development programs, liquidate all or a portion of our assets, and/or seek protection under the provisions of the U.S. Bankruptcy Code.Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:â—the number and characteristics of the product candidates we pursue;â—the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;â—the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;99Table of Contentsâ—the cost of manufacturing our product candidates and any drugs we successfully commercialize;â—our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;â—the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; â—expenses associated with the pending securities class action lawsuit, as well as other potential litigation; andâ—the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.See Item 1A â€œRisk Factorsâ€ for additional risks associated with our substantial capital requirements.Critical Accounting Policies and Significant Judgments and EstimatesOur consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reported period. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.Research and Development ExpensesAs part of the process of preparing our consolidated financial statements, we are required to estimate our prepaid and accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable 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 actual costs. The majority of our service providers require advance payments; however, some invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met. We make estimates of our prepaid expenses and accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated prepaid and accrued research and development expenses include fees paid to:â—vendors in connection with preclinical development activitiesâ—CMOs for the production of preclinical and clinical trial materials;â—CROs in connection with clinical trials; andâ—clinical trial sites.We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage 100Table of Contentspreclinical studies and clinical trials 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. In many instances payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In recognizing 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 the estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of prepaid and accrued research and development expenses.Recently Issued Accounting PronouncementsIn November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07, which is applicable to entities with a single reportable segment and will primarily require enhanced disclosures about significant segment expenses and enhanced disclosures in interim periods. The guidance in ASU 2023-07 will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023 and interim reporting periods in fiscal years beginning after December 31, 2024, with early adoption permitted. We are currently evaluating the impact that the adoption of ASU 2023-07 will have on its consolidated financial statements and disclosures.In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 which is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The guidance in ASU 2023-09 will be effective for annual reporting periods in fiscal years beginning after December 15, 2024. We are currently evaluating the impact that the adoption of ASU 2023-09 will have on its consolidated financial statements and disclosures.Item 7A. Quantitative and Qualitative Disclosures about Market RiskAs a â€œSmaller Reporting Companyâ€, this Item and the related disclosure is not required.â€‹101Table of ContentsItem 8. Consolidated Financial Statements and Supplementary DataOUTLOOK THERAPEUTICS, INC.ANNUAL REPORT ON FORM 10-KINDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTSâ€‹â€‹â€‹Pageâ€‹â€‹Report of Independent Registered Public Accounting Firm (PCAOB ID 185)103Consolidated Balance Sheets105Consolidated Statements of Operations106Consolidated Statements of Stockholdersâ€™ Equity (Deficit)107Consolidated Statements of Cash Flows108Notes to Consolidated Financial Statements109â€‹â€‹â€‹102Table of ContentsReport of Independent Registered Public Accounting FirmTo the Stockholders and Board of DirectorsOutlook Therapeutics, Inc.:Opinion on the Consolidated Financial StatementsWe have audited the accompanying consolidated balance sheets of Outlook Therapeutics, Inc. and subsidiaries (the Company) as of September 30, 2024 and 2023, the related consolidated statements of operations, stockholdersâ€™ 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 September 30, 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.Going ConcernThe accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred recurring losses from operations and negative cash flows from operations and has an accumulated deficit, that raise substantial doubt about its ability to continue as a going concern. Managementâ€™s plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.Basis for OpinionThese 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.Critical Audit Matter The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially

challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates. 103Table of ContentsEvaluation of prepaid and accrued research and development expenses As discussed in Note 3 to the consolidated financial statements, research and development costs are expensed as incurred and consist primarily of funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, as well as regulatory compliance costs. At the end of each reporting period, the Company compares the payments made to third-party service providers to the estimated progress towards completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense related to these costs.We identified the evaluation of prepaid and accrued research and development expenses for contract manufacturing organizations (CMOs) used by the Company for supply and manufacturing of pre-clinical and clinical trial materials and commercial materials, including manufacturing validation batches, as a critical audit matter. Specifically, evaluating the sufficiency of audit evidence obtained over associated costs incurred for the services provided by the CMOs required especially subjective auditor judgment due to the nature of evidence available regarding progress towards completion of underlying phases within the statements of work.The following are the primary procedures we performed to address this critical audit matter. We examined a sample of (1) statements of work, (2) payments, and (3) communications received from the CMOs related to the status of underlying phases within the statements of work, and compared them to the Company's schedules of costs incurred as of year-end. We also confirmed the status of underlying phases within the statements of work directly with the CMOs. We assessed the sufficiency of audit evidence obtained related to prepaid and accrued research and development expenses related to statements of work with the CMOs by evaluating the cumulative results of the audit procedures. Â /s/ KPMG LLPWe have served as the Companyâ€™s auditor since 2015.Philadelphia, PennsylvaniaDecember 27, 2024â€‹104Table of ContentsOutlook Therapeutics,Â Inc.Consolidated Balance Sheetsâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹SeptemberÂ 30,Â â€‹â€‹2024Â Â Â 2023â€‹â€‹â€‹â€‹â€‹â€‹â€‹Assetsâ€‹â€‹â€‹â€‹â€‹â€‹Current assets:â€‹â€‹â€‹â€‹â€‹â€‹Cash and cash equivalentsâ€‹$ 14,927,538â€‹$ 23,391,982Prepaid expenses and other current assetsâ€‹â€‹ 12,488,498â€‹â€‹ 7,587,216Total current assetsâ€‹â€‹ 27,416,036â€‹â€‹ 30,979,198â€‹â€‹â€‹â€‹â€‹â€‹Operating lease right-of-use assets, netâ€‹â€‹ 274,645â€‹â€‹ 26,172Equity method investmentâ€‹â€‹ 693,190â€‹â€‹ 793,932Other assetsâ€‹â€‹ 439,283â€‹â€‹ 501,299Total assetsâ€‹$ 28,823,154â€‹$ 32,300,601â€‹â€‹â€‹â€‹â€‹â€‹Liabilities and stockholdersâ€™ deficitâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Current liabilities:â€‹â€‹â€‹â€‹â€‹â€‹Unsecured convertible promissory noteâ€‹$ 29,440,000â€‹$ 35,551,000Finance lease liabilitiesâ€‹â€‹ â€”â€‹â€‹ 4,267Current portion of operating lease liabilitiesâ€‹â€‹ 50,907â€‹â€‹ â€”Accounts payableâ€‹â€‹ 7,968,725â€‹â€‹ 6,574,523Accrued expensesâ€‹â€‹ 3,237,468â€‹â€‹ 2,745,740Income taxes payableâ€‹â€‹ 1,856,629â€‹â€‹ 1,856,629Total current liabilitiesâ€‹â€‹ 42,553,729â€‹â€‹ 46,732,159â€‹â€‹â€‹â€‹â€‹â€‹Operating lease liabilitiesâ€‹â€‹ 246,922â€‹â€‹ â€”Warrant liabilityâ€‹â€‹ 59,099,013â€‹â€‹ 6,219Total liabilitiesâ€‹â€‹ 101,899,664â€‹â€‹ 46,738,378â€‹â€‹â€‹â€‹â€‹â€‹Commitments and contingencies (Note 8)â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Stockholdersâ€™ deficit:â€‹â€‹â€‹â€‹â€‹â€‹Preferred stock, par value $0.01 per share: 10,000,000 shares authorized, no shares issued and outstandingâ€‹â€‹ â€”â€‹â€‹ â€”Common stock, par value $0.01 per share; 60,000,000 shares authorized; 23,905,635 and 13,012,833 shares issued and outstanding at SeptemberÂ 30,Â 2024 and SeptemberÂ 30,Â 2023, respectivelyâ€‹â€‹ 239,057â€‹â€‹ 130,128Additional paid-in capitalâ€‹â€‹ 469,969,333â€‹â€‹ 453,350,281Accumulated deficitâ€‹â€‹ (543,284,900)â€‹â€‹ (467,918,186)Total stockholders' deficitâ€‹â€‹ (73,076,510)â€‹â€‹ (14,437,777)Total liabilities and stockholders' deficitâ€‹$ 28,823,154â€‹$ 32,300,601â€‹â€‹See accompanying notes to consolidated financial statementsâ€‹105Table of ContentsOutlook Therapeutics,Â Inc.Consolidated Statements of Operationsâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â 2023Operating expenses:â€‹â€‹â€‹â€‹â€‹â€‹Research and developmentâ€‹$ 41,763,047â€‹$ 26,452,942General and administrativeâ€‹â€‹ 29,940,188â€‹â€‹ 26,673,440Loss from operationsâ€‹â€‹ (71,703,235)â€‹â€‹ (53,126,382)Loss on equity method investmentâ€‹â€‹ 100,742â€‹â€‹ 10,998Interest incomeâ€‹â€‹ (906,150)â€‹â€‹ (971,480)Interest expense â€‹â€‹ 3,156,964â€‹â€‹ 2,531,228Loss on extinguishment of debtâ€‹â€‹ â€”â€‹â€‹ 577,659Change in fair value of promissory notesâ€‹â€‹ 2,457,153â€‹â€‹ 3,756,000Warrant related expenses (Note 9)â€‹â€‹ 37,490,012â€‹â€‹ â€”Change in fair value of warrant liabilityâ€‹â€‹ (38,638,042)â€‹â€‹ (50,919)Loss before income taxesâ€‹â€‹ (75,363,914)â€‹â€‹ (58,979,868)Income tax expenseâ€‹â€‹ 2,800â€‹â€‹ 2,800Net lossâ€‹$ (75,366,714)â€‹$ (58,982,668)â€‹â€‹â€‹â€‹â€‹â€‹Per share information:â€‹â€‹â€‹â€‹Net loss per share of common stock, basic and dilutedâ€‹$ (4.06)â€‹$ (4.72)Weighted average shares outstanding, basic and diluted â€‹â€‹ 18,548,813â€‹â€‹ 12,508,817â€‹See accompanying notes to consolidated financial statementsâ€‹â€‹106Table of ContentsOutlook Therapeutics,Â Inc.Consolidated Statements of Stockholdersâ€™ Equity (Deficit)â€‹Stockholdersâ€™Â Equity (Deficit)â€‹â€‹CommonÂ Stockâ€‹Additionalâ€‹Accumulatedâ€‹Total Stockholdersâ€™â€‹Â SharesÂ Â Â AmountÂ Â Â Paid-inÂ CapitalÂ Â Â DeficitÂ Â Â Equity (Deficit)Balance at October 1, 2022Â 11,365,486â€‹â€‹ 113,655â€‹â€‹ 417,558,434â€‹â€‹ (408,935,518)â€‹â€‹ 8,736,571Issuance of common stock in connection with conversion of convertible promissory noteÂ 625â€‹â€‹ 6â€‹â€‹ 24,994â€‹â€‹ â€”â€‹â€‹ 25,000Sale of common stock, net of issuance costs (Note 9)Â 1,646,722â€‹â€‹ 16,467â€‹â€‹ 30,219,834â€‹â€‹ â€”â€‹â€‹ 30,236,301Stock-based compensation expenseÂ â€”â€‹â€‹ â€”â€‹â€‹ 5,547,019â€‹â€‹ â€”â€‹â€‹ 5,547,019Net lossÂ â€”â€‹â€‹ â€”â€‹â€‹ â€”â€‹â€‹ (58,982,668)â€‹â€‹ (58,982,668)Balance at SeptemberÂ 30,Â 2023Â 13,012,833â€‹â€‹ 130,128â€‹â€‹ 453,350,281â€‹â€‹ (467,918,186)â€‹â€‹ (14,437,777)Issuance of common stock in connection with conversion of convertible promissory noteÂ 1,607,093â€‹â€‹ 16,072â€‹â€‹ 11,233,928â€‹â€‹ â€”â€‹â€‹ 11,250,000Sale of common stock, net of issuance costs (Note 9)Â 9,285,709â€‹â€‹ 92,857â€‹â€‹ â€”â€‹â€‹ â€”â€‹â€‹ 92,857Stock-based compensation expenseÂ â€”â€‹â€‹ â€”â€‹â€‹ 5,385,124â€‹â€‹ â€”â€‹â€‹ 5,385,124Net lossÂ â€”â€‹â€‹ â€”â€‹â€‹ â€”â€‹â€‹ (75,366,714)â€‹â€‹ (75,366,714)Balance at SeptemberÂ 30,Â 2024Â 23,905,635Â $ 239,057Â $ 469,969,333Â $ (543,284,900)Â $ (73,076,510)â€‹â€‹See accompanying notes to consolidated financial statements.â€‹â€‹â€‹â€‹107Table of ContentsOutlook Therapeutics,Â Inc.Consolidated Statements of Cash Flowsâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹Â Â Â 2024Â Â Â 2023OPERATING ACTIVITIESâ€‹â€‹â€‹â€‹â€‹â€‹Net lossâ€‹$ (75,366,714)â€‹$ (58,982,668)Adjustments to reconcile net loss to net cash used in operating activities:â€‹â€‹â€‹â€‹â€‹â€‹Depreciation and amortizationâ€‹â€‹ 113,859â€‹â€‹ 44,188Loss on extinguishment of debtâ€‹â€‹ â€”â€‹â€‹ 577,659Non-cash interest expenseâ€‹â€‹ 2,681,847â€‹â€‹ 2,529,830Stock-based compensationâ€‹â€‹ 5,385,124â€‹â€‹ 5,547,019Change in fair value of promissory notesâ€‹â€‹ 2,457,153â€‹â€‹ 3,756,000Warrant related expenses (Note 9)â€‹â€‹ 37,490,012â€‹â€‹ â€”Change in fair value of warrant liabilityâ€‹â€‹ (38,638,042)â€‹â€‹ (50,919)Loss on equity method investmentâ€‹â€‹ 100,742â€‹â€‹ 10,998Interest paid on debtâ€‹â€‹ â€”â€‹â€‹ (1,158,609)Changes in operating assets and liabilities:â€‹â€‹â€‹â€‹â€‹â€‹Prepaid expenses and other current assetsâ€‹â€‹ (4,901,282)â€‹â€‹ 2,616,925Other assetsâ€‹â€‹ (5,900)â€‹â€‹ (208,203)Operating lease liabilitiesâ€‹â€‹ 3,413â€‹â€‹ (26,995)Accounts payableâ€‹â€‹ 1,394,202â€‹â€‹ 3,083,038Accrued expensesâ€‹â€‹ 491,728â€‹â€‹ (711,661)Net cash used in operating activitiesâ€‹â€‹ (68,793,858)â€‹â€‹ (42,973,398)â€‹â€‹â€‹â€‹â€‹â€‹FINANCING ACTIVITIESâ€‹â€‹â€‹â€‹â€‹â€‹Proceeds from the sale of common stock and warrants to purchase common stock, net of issuance costsâ€‹â€‹ 60,333,681â€‹â€‹ 30,024,213Proceeds from debtâ€‹â€‹ â€”â€‹â€‹ 30,000,000Payments of finance lease obligationsâ€‹â€‹ (4,267)â€‹â€‹ (11,751)Repayment of debtâ€‹â€‹ â€”â€‹â€‹ (10,220,000)Payment of financing costsâ€‹â€‹ â€”â€‹â€‹ (823,894)Net cash provided by financing activitiesâ€‹â€‹ 60,329,414â€‹â€‹ 48,968,568Net (decrease) increase in cash and cash equivalentsâ€‹â€‹ (8,464,444)â€‹â€‹ 5,995,170Cash and cash equivalents at beginning of yearâ€‹â€‹ 23,391,982â€‹â€‹ 17,396,812Cash and cash equivalents at end of yearâ€‹$ 14,927,538â€‹$ 23,391,982Supplemental disclosure of cash flow information:â€‹â€‹â€‹â€‹â€‹â€‹Cash paid for interestâ€‹$ 475,000â€‹$ 1,160,008Supplemental schedule of non-cash financing activities:â€‹â€‹â€‹â€‹â€‹â€‹Convertible promissory note converted into common stockâ€‹$ 11,250,000â€‹$ 25,000Recognition of warrant liabilityâ€‹$ 97,730,836â€‹$ â€”Deferred offering costs amortizationâ€‹$ â€”â€‹$ 141,600Right-of-use asset and lease liability recognized for new operating lease liabilitiesâ€‹$ 294,416â€‹$ â€”â€‹See accompanying notes to consolidated financial statements.â€‹â€‹108Table of Contents1.Â Â Â Â Â Organization and OperationsDescription of the BusinessOutlook Therapeutics, Inc. (â€œOutlookâ€ or the â€œCompanyâ€) was incorporated in New Jersey on January 5, 2010, started operations in July 2011, reincorporated in Delaware by merging with and into a Delaware corporation in October 2015 and changed its name to â€œOutlook Therapeutics, Inc.â€ in November 2018. The Company is a biopharmaceutical company focused on developing and commercializing ONS-5010/LYTENAVAâ„¢ (bevacizumab-gamma), an ophthalmic formulation of bevacizumab for use in retinal indications. The Company is based in Iselin, New Jersey. â€‹In May 2024, the Company received Marketing Authorization from the European Commission for ONS-5010/LYTENAVA, an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (â€œAMDâ€) in the European Union (â€œEUâ€). Â Additionally, in July 2024 the Company also received marketing authorization for ONS-5010/LYTENAVA in the United Kingdom (â€œUKâ€) from the UK Medicines and Healthcare products Regulatory Agency (MHRA). ONS-5010/LYTENAVA is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK.In the fourth quarter of calendar 2023, the Company agreed to conduct an additional adequate and well-controlled clinical trial following discussions with the U.S. Food and Drug Administration (â€œFDAâ€) in support of the Companyâ€™s Biologics License Application (â€œBLAâ€) for ONS-5010/LYTENAVA. In December 2023, the Company submitted a Special Protocol Assessment (â€œSPAâ€) to the FDA for this study (NORSE EIGHT) seeking confirmation that, if successful, it will address the FDAâ€™s requirement for a second adequate and well-controlled clinical trial to support its planned resubmission of the ONS-5010/LYTENAVA BLA. In January 2024, the Company received confirmation that the FDA had reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA and that, if the NORSE EIGHT trial is successful, it would satisfy the FDAâ€™s requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the Complete Response Letter (â€œCRLâ€). In addition, through a Type A meeting and additional interactions, the Company has identified the approaches needed to resolve the chemistry, manufacturing and controls (â€œCMCâ€) comments in the CRL. In November 2024, the Company reported that Â ONS-5010/LYTENAVA did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the SPA. However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025.â€‹2.Â Â Â Â Â LiquidityThe Company has incurred recurring losses and negative cash flows from operations since its inception and has an accumulated deficit of $ 543,284,900 as of September 30, 2024. As of September 30, 2024, the Company had $31,352,857 of principal, accrued interest and exit fees due under an unsecured convertible promissory note issued in December 2022 (the â€œDecember 2022 Noteâ€), maturing on July 1, 2025, as amended. Â As a result, there is substantial doubt about the Companyâ€™s ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.In November 2024 and December 2024, the Company sold 1,000,000 shares of common stock under the BTIG ATM Offering and generated $1,742,343 in net proceeds after paying fees to BTIG and other issuance costs of $53,918. Refer to Note 9 for further details on the BTIG ATM Offering.Management does not believe that the Companyâ€™s existing cash and cash equivalents as of September 30, 2024, together with $1,742,343 in net proceeds from the sale of shares of common stock under the BTIG ATM Offering since September 30, 2024, are sufficient to fund the Companyâ€™s operations through one year from the Form 10-K filing date. As a result, there is substantial doubt about the Companyâ€™s ability to continue as a going concern and additional financing will be 109Table of Contentsneeded by the Company to fund its operations in the future and to commercially develop ONS-5010/LYTENAVA and to develop any other product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations, including but not limited to, the exercise of outstanding warrants to purchase shares of the Companyâ€™s common stock (subject to meeting the requirements for calling such warrants), proceeds from potential licensing and/or marketing arrangements or collaborations with pharmaceutical or other companies, sale of the development and commercial rights to the Companyâ€™s drug product candidates in regions outside of the U.S., the issuance of additional debt, the issuance of equity securities, including accessing capital through at-the-market offering agreements (refer to Note 9 for further details), and revenues from potential future product sales, if any. There can be no assurance that these future funding efforts will be successful. The Companyâ€™s consolidated financial statements do not include any adjustments that might be necessary if it is unable to continue as a going concern.The Companyâ€™s future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the Companyâ€™s ability to successfully begin marketing of its product candidates or complete revenue-generating partnerships with other companies; (iii) the success of its research and development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately, (v) regulatory approval and market acceptance of the Companyâ€™s proposed future products.â€‹3.Â Â Â Â Â Basis of Presentation and Summary of Significant Accounting PoliciesBasis of presentationThe accompanying consolidated financial statements have been prepared in conformity with U.S.Â generally accepted accounting principles (â€œGAAPâ€). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (â€œASCâ€) and Accounting Standards Updates (â€œASUâ€) of the Financial Accounting Standards Board (â€œFASBâ€). The accompanying consolidated financial statements include the accounts of the Company and Outlook Therapeutics Pty Ltd, its wholly-owned subsidiary incorporated in Australia (the â€œSubsidiaryâ€). All intercompany accounts and transactions have been eliminated in consolidation. The Company has determined the functional currency of the Subsidiary to be the U.S. dollar. The Company translates assets and liabilities of its foreign operations at exchange rates in effect at the balance sheet date. The Company records remeasurement gains and losses on monetary assets and liabilities, such as incentive and tax receivables and accounts payables, which are not in the functional currency of the operation. These remeasurement gains and losses are recorded in the consolidated statements of operations as they occur.Reverse stock splitEffective on March 14, 2024, the Company amended its amended and restated certificate of incorporation to implement a one-for-twenty reverse stock split of its common stock. As a result of the reverse stock split, the Company made corresponding adjustments to the share amounts under its employee incentive plans, outstanding options, and common stock warrant agreements with third parties. The disclosure of common shares and per common share data in the accompanying consolidated financial statements and related notes reflect the reverse stock split for all periods presented.Cash and cash equivalentsCash and cash equivalents include cash-on-hand and demand deposits with financial institutions and other short-term investments with maturities of less than three months when acquired and convertible to known cash amounts. At September 30, 2024 and 2023, the Companyâ€™s cash equivalents consist of a money market account.Equity method investmentThe Company accounts for equity investments where it owns a non-controlling interest, but has the ability to exercise significant influence, under the equity method of accounting. Under the equity method of accounting, the original cost of the investment is adjusted for the Companyâ€™s share of equity in the earnings or loss of the equity investee and reduced by dividends and distributions of capital received, unless the fair value option is elected, in which case the investment balance 110Table of Contentsis marked to fair value each reporting period and the impact of changes in fair value of the equity investment are reported in earnings. The Company has not elected the fair value option. The Company assesses its investment for other-than-temporary impairment when events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable and recognize an impairment loss to adjust the investment to its then-current fair value.Use of estimatesThe preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary.Fair value of financial instrumentsCertain assets and liabilities are carried at fair value under 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:â—Level 1 â€” Quoted prices in active markets for identical assets or liabilities.â—Level 2 â€” 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.â—Level 3 â€” Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.The assetâ€™s or liabilityâ€™s fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.At September 30, 2024 and 2023, the Companyâ€™s financial instruments included cash and cash equivalents, accounts payable, accrued expenses, unsecured convertible promissory note and warrant liabilities. The carrying amount of accounts payable, and accrued expenses approximates fair value due to the short-term maturities of these instruments.Fair Value OptionThe Company elected the fair value option to account for the December 2022 Note. Refer to Note 7 for further details on the December 2022 Note.LeasesAt lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term including any options to extend the lease that the Company is reasonably certain to exercise. The Company calculates the present value of lease payments using an incremental borrowing rate as the Companyâ€™s leases do not provide an implicit interest rate. The Companyâ€™s incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. At the lease 111Table of Contentscommencement date, the Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date. The Company may enter into leases with an initial term of 12 months or less (â€œShort-Term Leasesâ€). For Short-Term Leases, the Company records the rent expense on a straight-line basis and does not record the leases on the consolidated balance sheet. The Company had no Short-Term Leases as of September 30, 2024.After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement and (ii) the right-of-use lease asset based on the re-measured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received, and any initial direct costs incurred are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.Stock-based compensationThe Company measures equity classified stock-based awards based on the estimated fair value on the date of grant and recognizes compensation expense of those awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures of stock option awards as they occur.The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which is described more fully in NoteÂ 11. The fair value of each restricted stock award is measured as the fair value per share of the Companyâ€™s common stock on the date of grant.Research and developmentResearch and development costs are expensed as incurred and consist primarily of funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, and regulatory compliance costs. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs.Upfront milestone payments made to third parties who perform research and development services on the Companyâ€™s behalf are expensed as services are rendered. Costs incurred in obtaining technology licenses are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.Income taxesThe Company accounts for income taxes using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in theÂ years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.Net loss per shareBasic net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. For purposes of calculating diluted net loss per common share, the denominator includes both the weighted average common shares outstanding and the number of 112Table of Contentscommon stock equivalents if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include convertible debt, warrants, performance-based stock options and units, and stock options the treasury stock method. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares due to the Companyâ€™s losses.The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of SeptemberÂ 30, 2024 and 2023, as they would be antidilutive:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹As of SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â Â 2023â€‹Performance-based stock unitsâ€‹ â€”â€‹ 123â€‹Performance-based stock optionsâ€‹ 666,500â€‹ 35,000â€‹Stock optionsâ€‹ 1,946,646â€‹ 1,197,774â€‹Common stock warrantsâ€‹ 14,207,622â€‹ 366,427â€‹Convertible debtâ€‹ 1,171,100(i) 854,962(ii)â€‹(i)The calculation for potentially dilutive securities pertaining to convertible debt is as follows: $3,750,000 of outstanding principal and accrued interest as of September 30, 2024, is converted at a rate of $7.00, and the remaining amount is converted based on a fixed conversion price of $40.00 per share, which is subject to change as described in Note 7.(ii)The potentially dilutive securities related to convertible debt are calculated based on a fixed conversion price of $40.00 per share, which is subject to change as described in Note 7.â€‹Recently issued accounting pronouncementsIn November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07, which is applicable to entities with a single reportable segment and will primarily require enhanced disclosures about significant segment expenses and enhanced disclosures in interim periods. The guidance in ASU 2023-07 will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023 and interim reporting periods in fiscal years beginning after December 31, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-07 will have on its consolidated financial statements and disclosures.In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 which is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The guidance in ASU 2023-09 will be effective for annual reporting periods in fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact that the adoption of ASU 2023-09 will have on its consolidated financial statements and disclosures. Â â€‹113Table of Contents4.Â Â Â Â Â Fair Value MeasurementsThe following table presents the Companyâ€™s liabilities that are measured at fair value on a recurring basis:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹SeptemberÂ 30,Â 2024â€‹Â Â Â Â (Level 1)Â Â Â Â (Level 2)Â Â Â Â (Level 3)Liabilitiesâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Unsecured convertible promissory noteâ€‹$ â€”â€‹$ 29,440,000Warrant liabilityâ€‹â€‹ â€”â€‹â€‹ â€”â€‹â€‹ 59,099,013Totalâ€‹$ â€”â€‹$ â€”â€‹$ 88,539,013â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹SeptemberÂ 30,Â 2023â€‹â€‹(Level 1)Â Â Â Â (Level 2)Â Â Â Â (Level 3)Liabilitiesâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Unsecured convertible promissory noteâ€‹$ â€”â€‹$ â€”â€‹$ 35,551,000Warrant liabilityâ€‹â€‹ â€”â€‹â€‹ â€”â€‹â€‹ 6,219Totalâ€‹$ â€”â€‹$ â€”â€‹$ 35,557,219â€‹The table presented below is a summary of changes in the fair value of the Companyâ€™s Level 3 valuation for the warrant liability and the December 2022 Note for theÂ years ended SeptemberÂ 30, 2024 and 2023:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Unsecured Convertibleâ€‹â€‹â€‹â€‹Â Â Â Â Promissory NoteÂ Â Â Â WarrantsBalance at October 1, 2022â€‹$ â€”â€‹$ 57,138Fair value at issuanceâ€‹â€‹ 31,820,000â€‹â€‹ â€”Accrued interest converted to common stockâ€‹â€‹ (25,000)â€‹â€‹ â€”Change in fair valueâ€‹â€‹ 3,756,000â€‹â€‹ (50,919)Balance at SeptemberÂ 30,Â 2023â€‹â€‹ 35,551,000â€‹â€‹ 6,219Issued in connection with sale of common stockâ€‹â€‹ â€”â€‹â€‹ 97,730,836Promissory note maturity extension fee added to outstanding balanceâ€‹â€‹ 2,681,847â€‹â€‹ â€”Principal and accrued interest converted to common stockâ€‹â€‹ (11,250,000)â€‹â€‹ â€”Change in fair valueâ€‹â€‹ 2,457,153â€‹â€‹ (38,638,042)Balance at SeptemberÂ 30,Â 2024â€‹$ 29,440,000â€‹$ 59,099,013â€‹As further described in Note 7, the Company elected the fair value option to account for the December 2022 Note. The fair value of the December 2022 Note is estimated using a binomial lattice model, which evaluates the payouts under hold, convert or call decisions. Significant estimates in the binomial lattice model include the Companyâ€™s stock price, volatility, risk-free rate of return, and credit-adjusted discount rate. â€‹The fair values of the December 2022 Note as of September 30, 2024 and 2023 were estimated using a binomial lattice model with the following assumptions:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹September 30,â€‹â€‹2024â€‹2023â€‹Term (years)â€‹â€‹ 0.8â€‹â€‹â€‹ 0.3â€‹Volatilityâ€‹â€‹ 91.0%Â Â â€‹â€‹ 71.0%Risk-free rateâ€‹â€‹ 4.2%â€‹â€‹ 5.5%Dividend yieldâ€‹â€‹ â€”%â€‹â€‹ â€”%Credit-adjusted discount rateâ€‹â€‹ 20.4%â€‹â€‹ 22.8%Stock priceâ€‹$ 5.34â€‹â€‹$ 4.40â€‹â€‹114Table of ContentsThe warrants related to the Note and Warrant Purchase Agreement dated December 22, 2017 are classified as liabilities as the warrants include cash settlement features at the option of the holders under certain circumstances. The warrants issued in connection with private placements that closed on March 18, 2024 and April 15, 2024 are classified as liabilities as the Company assessed that they are not indexed to the Companyâ€™s own stock and must be classified as liabilities. For further details on the evaluation refer to Note 9. â€‹The above warrant liabilities are revalued each reporting period with the change in fair values recorded in the accompanying consolidated statements of operations until the warrants are exercised or expire. The fair values of the warrant liabilities are estimated using the Black-Scholes option pricing model using the following weighted average assumptions:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹September 30,â€‹â€‹2024â€‹2023â€‹Risk-free interest rateâ€‹â€‹ 3.58%Â Â â€‹â€‹ 5.30%Remaining contractual term of warrants (years)â€‹â€‹ 4.5â€‹â€‹â€‹ 1.4â€‹Expected volatilityâ€‹â€‹ 125.0%â€‹â€‹ 158.3%Annual dividend yieldâ€‹â€‹ â€”%â€‹â€‹ â€”%Fair value of common stock (per share)â€‹$ 5.34â€‹â€‹$ 4.40â€‹â€‹â€‹â€‹5. Â Â Â Â Â Equity Method Investmentâ€‹In connection with the execution of a stock purchase agreement with Syntone Ventures LLC (â€œSyntone Venturesâ€), the U.S. based affiliate of Syntone Technologies Group Co. Ltd. (â€œSyntone PRCâ€) on May 22, 2020, the Company and Syntone PRC entered into a joint venture agreement pursuant to which they agreed to form a Peopleâ€™s Republic of China (â€œPRCâ€) joint venture, Beijing Syntone Biopharma Ltd (â€œSyntone JVâ€), that is 80% owned by Syntone PRC and 20% owned by the Company. As the Company can exert significant influence over, but does not control, Syntone JVâ€™s operations through voting rights or representation on Syntone JVâ€™s board of directors, the Company accounts for this investment using the equity method of accounting. Upon formation of Syntone JV in April 2021, the Company entered into a royalty-free license with Syntone JV for the development, commercialization and manufacture of ONS-5010/LYTENAVA in the greater China market, which includes Hong Kong, Taiwan and Macau.â€‹The Company made the initial investment of $900,000 in June 2020 and is committed to making capital contributions to Syntone JV of approximately $2,100,000, based upon the development plan contemplated in the license agreement. The maximum exposure to a loss as a result of the Companyâ€™s involvement in Syntone JV is limited to the initial investment and the future capital contributions totaling approximately $2,100,000. â€‹6.Â Â Â Â Â Accrued ExpensesAccrued expenses consists of:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Â Â Â Â SeptemberÂ 30,Â â€‹â€‹2024Â Â Â Â 2023Compensationâ€‹$ 1,012,962â€‹$ 919,970Professional feesâ€‹â€‹ 1,798,767â€‹â€‹ 165,192Research and developmentâ€‹â€‹ 41,373â€‹â€‹ 1,234,192Other accrued expensesâ€‹â€‹ 384,366â€‹â€‹ 426,386â€‹â€‹$ 3,237,468â€‹$ 2,745,740â€‹â€‹115Table of Contents7.Â Â Â Â Â DebtDebt consists of:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Â Â Â SeptemberÂ 30,Â â€‹â€‹2024Â Â Â 2023Unsecured convertible promissory note (measured at fair value)â€‹$ 29,440,000â€‹$ 35,551,000Less: current portionâ€‹â€‹ (29,440,000)â€‹â€‹ (35,551,000)Long-term debtâ€‹$ â€”â€‹$ â€”â€‹December 2022 NoteOn December 22, 2022, the Company entered into a Securities Purchase Agreement and issued the December 2022 Note with a face amount of $31,820,000 to Streeterville Capital, LLC (the â€œLenderâ€), the holder of the Companyâ€™s unsecured promissory note issued in November 2021 (the â€œNovember 2021 Noteâ€). The December 2022 Note has an original issue discount of $1,820,000. The Company received net proceeds of $18,052,461 upon the closing on December 28, 2022 after deducting the Lenderâ€™s transaction costs in connection with the issuance and a full payment of the remaining outstanding principal and accrued interest on the November 2021 Note. The November 2021 Note was cancelled upon repayment. See below for additional disclosures relating to the November 2021 Note.In December 2023, the Company extended the maturity of the December 2022 Note from January 1, 2024 to April 1, 2024. The Company incurred a $475,000 extension fee. The December 2022 Note bore interest at 9.5% per annum through April 1, 2024. The December 2022 Note contains customary covenants, including a restriction on the Companyâ€™s ability to pledge certain of the Companyâ€™s assets, subject to certain exceptions, without the Lenderâ€™s consent. Beginning on April 1, 2023, the Lender had the right to convert the December 2022 Note at the Conversion Price (as defined below). The principal amount and conversion price of the December 2022 Note were subject to adjustment upon certain triggering events. In addition, the Company had the right to convert all or any portion of the outstanding balance under the December 2022 Note into shares of common stock at the Conversion Price if certain conditions have been met at the time of conversion, including if at any time after the six-month anniversary of the closing date, the daily volume-weighted average price of the common stock on Nasdaq equals or exceeds $50.00 per share (subject to adjustments for stock splits and stock combinations) for a period of 30 consecutive trading days. Payments may be made by the Company (i) in cash, (ii) in shares of common stock, with the number of shares being equal to the portion of the applicable payment amount divided by the Conversion Price (as defined below), or (iii) a combination of cash and shares of common stock. Any payments made by the Company in cash, including prepayments or repayment at maturity, will be subject to an additional fee of 7.5%. Upon the occurrence of certain events described in the December 2022 Note, including, among others, the Companyâ€™s failure to pay amounts due and payable under the December 2022 Note, events of insolvency or bankruptcy, failure to observe covenants contained in the Securities Purchase Agreement and the December 2022 Note, breaches of representations and warranties in the Securities Purchase Agreement, and the occurrence of certain transactions without the Lenderâ€™s consent (each such event, a â€œTrigger Eventâ€), the Lender shall have the right, subject to certain exceptions, to increase the balance of the December 2022 Note by 10% for a Major Trigger Event (as defined in the December 2022 Note) and 5% for a Minor Trigger Event (as defined in the December 2022 Note). If a Trigger Event is not cured within ten (10) trading days of written notice thereof from the Lender, it will result in an event of default (such event, an â€œEvent of Defaultâ€). Following an Event of Default, the Lender may accelerate the December 2022 Note such that all amounts thereunder become immediately due and payable, and interest shall accrue at a rate of 22% annually until paid. Prior to April 1, 2024, under the December 2022 Note, â€œConversion Priceâ€ meant, prior to a Major Trigger Event, $40.00 per share (subject to adjustment for stock splits and stock combinations), and following a Major Trigger Event, the lesser of (i) $40.00 per share (subject to adjustment for stock splits and stock combinations), and (ii) 90% multiplied by the lowest closing bid price of the Companyâ€™s common stock in the three trading days prior to the date on which the conversion notice is delivered. If the Conversion Price is below $3.51 per share, the Company will be required to satisfy a conversion notice from the Lender in cash. Subject to certain exceptions, while the December 2022 Note is outstanding, the Lender will have a consent right on any future variable rate transactions or any debt and a 10% participation right in any future debt or equity financings.116Table of ContentsOn January 22, 2024, the Company entered into an amendment to the December 2022 Note (the â€œJanuary 2024 Note Amendmentâ€) with the Lender, which became effective on April 1, 2024 after satisfaction of certain conditions, including various required stockholder approvals and the closing of the private placement on March 18, 2024. The maturity of the December 2022 Note was extended to July 1, 2025. An extension fee of $2,681,847 (calculated as 7.5% of the outstanding balance of the December 2022 Note) was added to the outstanding balance on March 18, 2024. The extension fee was included in interest expense in the consolidated statement of operations for the year ended September 30, 2024.Under the January 2024 Note Amendment, the initial conversion price with respect to $15,000,000 in aggregate principal amount of the December 2022 Note was changed to $7.00, the price per share in the private placement that closed on March 18, 2024 and the remaining aggregate principal amount has a conversion price of $40.00 per share. Effective April 1, 2024, the December 2022 Note bears interest at the prime rate (as published in the Wall Street Journal) plus 3% (subject to a floor of 9.5%) and the Company has an obligation to repay at least $3,000,000 of the outstanding balance of the December 2022 Note for each calendar quarter beginning with the second calendar quarter of 2024 (subject to adjustment for conversions by the Lender and to payment of an exit fee as set forth in the January 2024 Note Amendment) and continuing until the December 2022 Note is repaid in full. During the year ended September 30, 2024, an aggregate of principal and accrued interest totaling $11,250,000 of the December 2022 Note was converted into 1,607,093 shares of the Companyâ€™s common stock.The Company elected to account for the December 2022 Note at fair value (Note 4) and was not required to bifurcate the conversion option as a derivative and as a result the original issue discount of $1,820,000 and debt issuance costs were written off upon election to fair value and accounted for as interest. During the year ended September 30, 2024, the Company recognized $3,156,847 of interest expense related to extension fees. During the year ended September 30, 2023, the Company recognized $2,074,964 of interest expense related to original issue discount of

$1,820,000 and other third party debt issuance costs of $254,964.November 2021 NoteOn November 16, 2021, the Company received $10,000,000 in net proceeds from the issuance of the November 2021 Note with a face amount of $10,220,000. Debt issuance costs totaling $820,000 were recorded as debt discount and were deducted from the principal in the accompanying consolidated balance sheets. The debt discount was amortized as a component of interest expense over the term of the underlying debt using the effective interest method. The note bore interest at a rate of 9.5% per annum compounding daily and was set to mature on January 1, 2023. The Company could prepay all or a portion of the note at any time by paying 105% of the outstanding balance elected for prepayment.As discussed above, the November 2021 Note was cancelled using proceeds from the December 2022 Note issued to the same lender. The total repayment was $11,947,539, which represented 105% of the outstanding balance and included $1,158,609 of interest expense. The transaction has been accounted for as an extinguishment of the November 2021 Note. As a result, the Company recorded a loss on debt extinguishment of $577,659, which included $8,729 of unamortized debt discount, and prepayment fees of $568,930.During the year ended September 30, 2023, the Company recognized $454,866 of interest expense related to the unsecured promissory note, of which $190,775 was related to the amortization of debt discount. â€‹8.Â Â Â Â Â Commitments and ContingenciesSelexis Commercial License AgreementsIn AprilÂ 2013, the Company entered into commercial license agreements with Selexis for each of the ONS-3010, ONS-1045 and ONS-1050 biosimilar product candidates (which agreements were subsequently amended on MayÂ 21, 2014). Under the terms of each commercial license agreement, the Company acquired a non-exclusive worldwide license under the Selexis Technology to use the applicable Selexis expression technology along with the resulting Selexis 117Table of Contentsmaterials/cell lines, each developed under the research license, to manufacture and commercialize licensed and final products, with a limited right to sublicense.The Company paid an upfront licensing fee to Selexis for each commercial license and also agreed to pay a fixed milestone payment for each licensed product. In addition, the Company is required to pay a low single-digit royalty on a final product-by-final product and country-by-country basis, based on worldwide net sales of such final products by the Company or any of the Companyâ€™s affiliates or sublicensees during the royalty term. The royalty term for each final product in each country is the period commencing from the first commercial sale of the applicable final product in the applicable country and ending on the expiration of the specified patent coverage. At any time during the term, the Company has the right to terminate its royalty payment obligation by providing written notice to Selexis and paying Selexis a royalty termination fee.Each of the Companyâ€™s commercial agreements with Selexis will expire upon the expiration of all applicable Selexis patent rights. Either party may terminate the related agreement in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, winding up or similar circumstances. Either party may also terminate the related agreement under designated circumstances if the Selexis Technology infringes third-party intellectual property rights. In addition, the Company has the right to terminate each of the commercial agreements at any time at its convenience; however, with respect to the agreements relating to ONS-3010 and ONS-1045, this right is subject to the licenseeâ€™s consent pursuant to a corresponding letter the Company executed in conjunction with the standby agreement entered into between Selexis and Laboratories Liomont, S.A. de C.V. (â€œLiomontâ€) in NovemberÂ 2014.The standby agreement permits Liomont to assume the license under the applicable commercial agreement for Mexico upon specified triggering events involving the Companyâ€™s bankruptcy, insolvency or similar circumstances.Technology LicenseThe Company entered into a technology license agreement with Selexis that will require milestone payments of $332,779 (based on an exchange rate on SeptemberÂ 30, 2024 for converting Swiss Francs to U.S. dollars) to the licensor by the Company upon achievement of certain clinical milestones and pay a single digit royalty on net sales by the Company utilizing such technology. The Company also has the contractual right to buy out the royalty payments at a future date.LitigationOn November 3, 2023, a securities class action lawsuit was filed against the Company and certain of its officers in the United States District Court for the District of New Jersey. The class action complaint alleges violations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements made by the Company related to the Companyâ€™s BLA during the period from August 3, 2021 through August 29, 2023. The complaint alleges, among other things, that the Company violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by failing to disclose that there was an alleged lack of evidence supporting ONS-5010/LYTENAVA as a treatment for wet AMD and that the Company and/or their manufacturing partner had deficient CMC controls for ONS-5010/LYTENAVA, which remained unresolved at the time the Companyâ€™s BLA was re-submitted to the FDA and, as a result, the FDA was unlikely to approve the Companyâ€™s BLA, and that the Companyâ€™s stock price dropped when such information was disclosed. The plaintiffs in the class action complaint seek damages and interest, and an award of reasonable costs, including attorneysâ€™ fees. Defendantsâ€™ motion to dismiss is currently pending before the court.On October 10, 2024, certain of the companyâ€™s officers and directors were named as defendants in a shareholder derivative action filed in the District Court of the District of Delaware. Â The derivative complaint alleges that defendants breached their fiduciary duties by causing and/or allowing the Company to violate federal securities laws based on the same alleged misstatements as the securities class action. Â The derivative complaint also alleges defendants violated Section 14(a) of the Exchange Act, as well as claims for contribution, unjust enrichment, and waste of corporate assets. Â The derivative complaint seeks unspecified damages, corporate governance reforms, restitution, contribution, attorneysâ€™ fees, and other costs.118Table of ContentsThe pending lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. The Company could be forced to expend significant resources in the defense of the pending lawsuits and any additional lawsuits, and the Company may not prevail. In addition, the Company may incur substantial legal fees and costs in connection with such lawsuits. The Company currently is not able to estimate the possible cost to it from these matters, as the pending lawsuits are currently at an early stage, and the Company cannot be certain how long it may take to resolve the pending lawsuits or the possible amount of any damages that the Company may be required to pay. Such amounts could be material to the Companyâ€™s financial statements if it does not prevail in the defense of the pending lawsuits and any other related lawsuits, or even if it does prevail. The Company has not established any reserve for any potential liability relating to the pending lawsuits and any other related lawsuits. It is possible that the Company could, in the future, incur judgments or enter into settlements of claims for monetary damages.LeasesCorporate office In March 2021, the Company entered into a three-year term corporate office lease in Iselin, New Jersey that ended on April 30, 2024.In March 2024, the Company entered into a five-year term corporate office lease for its new corporate headquarters in Iselin, New Jersey that commenced on May 1, 2024.Equipment leasesâ€‹As of September 30, 2024, all equipment leases had expired. The Company had equipment leases with terms between 12 and 36 months and had recorded those leases as finance leases. The equipment leases bore interest between 4.0% and 13.0% per annum. Payments due under the lease contracts included minimum payments that the Company was obligated to make under the non-cancelable initial terms of the leases as the renewal terms were at the Companyâ€™s option. Lease expense was recorded as research and development or general and administrative based on the use of the leased asset.â€‹The components of lease cost for the years ended September 30, 2024 and 2023 were as follows:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â Â 2023Lease cost:Â â€‹Â Â Â Â â€‹Â Â Interest on lease liabilitiesâ€‹$ 116â€‹$ 1,399Total finance lease costâ€‹Â 116â€‹Â 1,399Operating lease costâ€‹Â 57,973â€‹Â 44,867Total lease costâ€‹$ 58,089â€‹$ 46,266â€‹119Table of ContentsAmounts reported in the consolidated balance sheets for leases where the Company is the lessee were as follows:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Â Â Â Â SeptemberÂ 30,Â â€‹â€‹2024Â Â Â Â 2023Operating leases:Â â€‹â€‹Â â€‹Â Â Right-of-use assetâ€‹$ 274,645â€‹$ 26,172Operating lease liabilitiesâ€‹Â 297,829â€‹Â â€”Finance leases:â€‹Â Â Â Â â€‹Â Â Right-of-use assetâ€‹$ â€”â€‹$ â€”Financing lease liabilitiesâ€‹Â â€”â€‹Â 4,267Weighted-average remaining lease term (years):â€‹Â Â Â Â â€‹Â Â Â Operating leasesâ€‹â€‹ 4.6â€‹â€‹ 0.6Finance leasesâ€‹Â â€”â€‹Â 0.3Weighted-average discount rate:â€‹Â Â Â Â â€‹Â Â Â Operating leasesâ€‹â€‹9.9%â€‹â€‹7.5%Finance leasesâ€‹Â â€”â€‹Â 13.0%â€‹Other information related to leases for the years ended September 30, 2024 and 2023 are as follows:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â Â 2023Cash paid for amounts included in the measurement of lease obligations:Â â€‹â€‹Â â€‹Â Â Operating cash flows from finance leasesâ€‹$ 116â€‹$ 1,399Operating cash flows from operating leasesâ€‹Â 14,514â€‹Â 27,675Financing cash flows from finance leasesâ€‹Â 4,267â€‹Â 11,751Right-of-use assets obtained in exchange for lease obligations:â€‹Â Â Â Â â€‹Â Â Â Operating leasesâ€‹$ 294,416â€‹$ â€”â€‹Future minimum payments under noncancelable leases at SeptemberÂ 30, 2024 are as follows for theÂ years ending SeptemberÂ 30:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Operating leases2025â€‹â€‹â€‹â€‹â€‹$ 78,0912026â€‹â€‹â€‹â€‹â€‹â€‹â€‹ 79,9542027â€‹â€‹â€‹â€‹â€‹â€‹â€‹ 81,8172028â€‹â€‹â€‹â€‹â€‹â€‹â€‹ 83,6802029â€‹â€‹â€‹â€‹â€‹â€‹â€‹ 49,447Total undiscounted lease paymentsâ€‹â€‹â€‹â€‹â€‹â€‹â€‹ 372,989Less: Imputed interestâ€‹â€‹â€‹â€‹â€‹Â 75,160Total lease obligationsâ€‹â€‹â€‹â€‹â€‹$ 297,829â€‹Employee Benefit PlanThe Company maintains a defined contribution 401(k)Â plan (the â€œPlanâ€) in which employees may contribute up to 100% of their salary and bonus, subject to statutory maximum contribution amounts. The Company matches 100% of the first 3% of employee contributions. The Company assumes all administrative costs of the Plan. For theÂ years ended SeptemberÂ 30, 2024 and 2023, the expense relating to the matching contribution was $177,309 and $136,914, respectively.â€‹120Table of Contents9.Â Â Â Â Stockholdersâ€™ EquityCommon stockOn March 7, 2024, following receipt of stockholder approval at the Companyâ€™s 2024 annual meeting of stockholders, the number of authorized shares of common stock under the Companyâ€™s Certificate of Incorporation was increased from 21,250,000 shares to 60,000,000 shares.On March 18, 2024, in a private placement (the â€œPrivate Placementâ€) pursuant to a securities purchase agreement entered in January 2024 with certain institutional and accredited investors, including GMS Ventures and Investments (â€œGMS Venturesâ€), the Companyâ€™s largest stockholder, the Company issued an aggregate of 8,571,423 shares of common stock and warrants to purchase an aggregate of 12,857,133 shares of common stock at a purchase price per share of $7.00 per share and accompanying warrant to purchase one and one-half shares of common stock for $55,498,311 in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 2,305,714 shares of common stock and warrants to purchase an aggregate of 3,458,571 shares of common stock in the Private Placement. The Warrants have an exercise price of $7.70 per share of common stock and will expire on March 18, 2029.On April 15, 2024, in a private placement with Syntone pursuant to a securities purchase agreement entered into in January Â 2024 (the â€œSyntone Private Placementâ€), the Company issued 714,286 shares of common stock and accompanying warrants to purchase 1,071,429 shares of common stock for $4,835,371 in net proceeds on substantially the same terms as those in the Private Placement. The warrants have an exercise price of $7.70 per share of common stock and will expire on April 15, 2029.The Company evaluated the equity classification for the common stock warrants and considered the conditions as prescribed within ASC 815-40,Â Derivatives and Hedging, Contracts in an Entityâ€™s own EquityÂ (â€œASC 815-40â€). The Company determined that the warrants did not meet the â€œfixed for fixedâ€ settlement provision set forth in Step 2 of the indexation guidance and as a result they are not indexed to the Companyâ€™s own stock and must be classified as liabilities. The warrants were measured at fair value at issuance and recorded as a liability and will be remeasured to fair value at each subsequent reporting date, with changes in fair value recorded in current earnings. The net proceeds from the Private Placement were allocated first to the warrants at fair value, with the residual amount recorded as common stock at par value. The Company will continue to classify such warrants as liabilities until they are exercised, expire, or are no longer required to be classified as liabilities.â€‹In December 2022, in a registered direct equity offering to certain institutional and accredited investors, including GMS Ventures, the Company issued 1,423,041 shares of common stock at a purchase price per share of $17.568 for $23,208,679 in net proceeds after payment of placement agent fees and other offering costs. GMS Ventures purchased an aggregate of 711,520 shares of common stock in the registered direct equity offering. In connection with the registered direct equity offering, the Company issued to M.S. Howells & Co., the placement agent, warrants to purchase up to an aggregate of 25,787 shares of common stock at an exercise price of $21.00 per share, which warrants have a three-year term.Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Companyâ€™s stockholders. Subject to preferences that may apply to any outstanding preferred stock, holders of common stock are entitled to receive ratably any dividends that the Companyâ€™s board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. No dividends had been declared through SeptemberÂ 30, 2024.H.C. Wainwright & Co. At-the-Market Offering AgreementOn March 26, 2021, the Company entered into an At-the-Market Offering Agreement with H.C. Wainwright & Co., as sales agent (â€œWainwrightâ€), (the â€œWainwright ATM Agreementâ€ or the â€œWainwright ATM Offeringâ€), under which the Company may issue and sell shares of its common stock from time to time through Wainwright as sales agent. The Company filed a prospectus supplement, dated March 26, 2021, with the Securities and Exchange Commission pursuant to which the Company may offer and sell shares of common stock having an aggregate offering price of up to up to $40,000,000 from time to time through Wainwright. The Company incurred financing costs of $197,654 which were 121Table of Contentscapitalized and were being reclassified to additional paid in capital on a pro rata basis when the Company sold common stock under the Wainwright ATM Offering.Under the Wainwright ATM Offering, the Company paid Wainwright a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the Wainwright ATM Agreement. The Company terminated the Wainwright ATM Agreement effective May 15, 2023. As a result, the Company wrote off unamortized deferred costs under the Wainwright ATM Agreement. During the year ended September 30, 2023, the Company sold 44,769 shares of common stock under the Wainwright ATM Offering and generated $1,089,105 in net proceeds after paying fees to Wainwright of $38,799. BTIG, LLC At-the-Market Offering AgreementOn May 16, 2023, the Company entered into an At-the-Market Sales Agreement with BTIG, LLC (â€œBTIGâ€), as sales agent (the â€œBTIG ATM Agreementâ€ or the â€œBTIG ATM Offeringâ€), under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $100,000,000 from time to time through BTIG. The Company incurred financing costs of $353,688, which were capitalized and are being reclassified to additional paid in capital on a pro rata basis when the Company sells common stock under the BTIG ATM Offering. As of September 30, 2024, $331,512 of such deferred costs are included in other assets on the consolidated balance sheets.Under the BTIG ATM Agreement, the Company pays BTIG a commission equal to 3.0% of the aggregate gross proceeds of any sales of common stock under the BTIG ATM Agreement. The offering of common stock pursuant to the BTIG ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the BTIG ATM Agreement or (ii) termination of the BTIG ATM Agreement in accordance with its terms. During the year ended September 30, 2024, no shares of common stock were sold under the BTIG ATM Offering. During the year ended September 30, 2023, the Company sold 178,911 shares of common stock under the BTIG ATM Offering and generated $6,080,088 in net proceeds after paying fees to BTIG and other issuance costs of $188,044.Common stock warrantsAs of SeptemberÂ 30, 2024, the Company had the following warrants outstanding to acquire shares of its common stock:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Shares ofâ€‹â€‹â€‹â€‹â€‹common stockâ€‹â€‹â€‹â€‹â€‹issuable uponâ€‹â€‹â€‹â€‹â€‹exercise ofâ€‹Exercise PriceExpiration DateÂ Â Â Â warrantsÂ Â Â Â Per ShareDecember 22, 2024(i) 13,850â€‹$ 240.00February 24, 2025â€‹ 8,642â€‹$ 25.40April 13, 2025(i) 7,284â€‹$ 240.00May 31, 2025(i) 3,121â€‹$ 240.00June 22, 2025â€‹ 9,563â€‹$ 30.38December 28, 2025â€‹ 25,787â€‹$ 21.00January 28, 2026â€‹ 12,576â€‹$ 25.00February 2, 2026â€‹ 93,238â€‹$ 25.00November 23, 2026â€‹ 104,999â€‹$ 31.25March 18, 2029(ii) 12,857,133â€‹$ 7.70April 15, 2029(ii) 1,071,429â€‹$ 7.70â€‹â€‹ 14,207,622â€‹â€‹â€‹â€‹â€‹(i)The warrants were issued in connection with the convertible senior secured notes originally issued pursuant to the certain Note and Warrant Purchase Agreement dated December 22, 2017 and are classified as liabilities on the accompanying consolidated balance sheets, as the warrants include cash settlement features at the option of the holders under certain circumstances. Refer to Note 4 for fair value measurements disclosures.â€‹122Table of Contents(ii)The warrants were issued in connection with private placements that closed on March 18, 2024 and April 15, 2024 and are exercisable only for cash, except in limited circumstances, at any time after the date of issuance. The Company evaluated the warrants under ASC 815-40 guidance and determined that the warrants did not meet Step 2 of the indexation. As a result they are not indexed to the Companyâ€™s own stock and must be classified as liabilities. Refer to the disclosure above under the header â€œCommon stockâ€ for further details.A holder of warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than a specified percentage of the outstanding common stock (4.99%, 9.99% or 19.99%, as applicable), immediately after giving effect to such exercise, which may be increased or decreased at the holdersâ€™ option (not to exceed 19.99%), effective 61 days after written notice to the Company. In addition, the Company may require the holders to cash exercise the warrants under certain circumstances as follows: (i) if the daily volume weighted average price (the â€œVWAPâ€) of the common stock equals or exceeds $20.00 per share (subject to adjustment in the event of stock splits, combinations or similar events, such as the reverse stock split implemented prior to closing) for 30 consecutive days (the â€œStock Price Conditionâ€) at any time after the Company publicly announces topline data from its NORSE EIGHT clinical trial evidencing satisfaction of the trialâ€™s primary endpoints (the â€œNORSE EIGHT Announcementâ€), upon the consent of a majority of the members of the Companyâ€™s board of directors, the Company may require the holders to exercise up to 20% of the aggregate number of warrants issued to such holder on the issue date; and (ii) the Company may require up to the remainder of the warrants be exercised (A) if the Stock Price Condition is satisfied at any time after the Company publicly announces approval from the FDA of its BLA for ONS-5010/LYTENAVA, upon the consent of a majority of the members of the board of directors or (B) if the Stock Price Condition is satisfied at any time after the NORSE EIGHT Announcement, upon the unanimous consent of the members of the Companyâ€™s Board of Directors present at a duly called meeting.â€‹â€‹10.Â Â Â Preferred StockOn May 13, 2024, the

Company filed a Certificate of Elimination to its Certificate of Incorporation, as then amended, with the Secretary of State of the State of Delaware to eliminate from the Certificate of Incorporation all matters set forth in the Certificates of Designation filed with the Secretary of State of the State of Delaware on September 8, 2017 (with respect to its Series A Convertible Preferred Stock and the Series B Convertible Preferred Stock) and July 18, 2018, as amended on March 19, 2020 (with respect to its Series A-1 Convertible Preferred Stock) and returning each of the Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series A-1 Convertible Preferred Stock to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series. There were no outstanding shares of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock or Series A-1 Convertible Preferred Stock as of May 13, 2024. Immediately following the filing of the Certificate of Elimination, the Company filed a Restated Certificate of Incorporation of the Company with the Secretary of State of the State of Delaware, which restates and integrates but does not further amend the Companyâ€™s Certificate of Incorporation, as then amended. The number of authorized shares of preferred stock under the Companyâ€™s Certificate of Incorporation is 10,000,000 shares.â€‹11.Â Â Â Stock-Based Compensation2011 Equity Incentive PlanThe Companyâ€™s 2011 Equity Compensation Plan (the â€œ2011 Planâ€) provided for the Company to sell or issue restricted common stock, restricted stock units (â€œRSUsâ€), performance-based awards (â€œPSUsâ€), cash-based awards or to grant stock options for the purchase of common stock to officers, employees, consultants and directors of the Company. The 2011 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. As of September 30, 2024, there were no equity awards outstanding under the 2011 Plan. In light of the DecemberÂ 2015 adoption of the 2015 Equity Incentive Plan, (the â€œ2015 Planâ€) no future awards under the 2011 Plan will be granted.2024 Equity Incentive PlanIn DecemberÂ 2015, the Company adopted the 2015 Plan. The 2015 Plan provided for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards and other forms of equity 123Table of Contentscompensation to Company employees, directors and consultants. In August 2024, the Companyâ€™s stockholders approved the amendment and restatement of the 2015 Plan and, in connection with amending and restating the 2015 Plan, the name of the 2015 Plan was updated to the Outlook Therapeutics, Inc. 2024 Equity Incentive Plan (the â€œ2024 Planâ€). The 2024 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards and other forms of equity compensation to Company employees, directors and consultants. The aggregate number of shares of common stock authorized for issuance pursuant to the Companyâ€™s 2024 Plan is 7,293,901. As of September 30, 2024, 4,680,755 shares remained available for grant under the 2024 Plan.Stock options and RSUs granted under the Company's 2024 Plan generally vest over a period of one to four years from the date of grant and, in the case of stock options, have a term of 10 years. The Company recognizes the grant date fair value of each option and share of RSU over its vesting period.â€‹The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations for the years ended September 30, 2024 and 2023:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â Â 2023Research and developmentâ€‹$ 800,956â€‹$ 986,598General and administrativeâ€‹â€‹ 4,584,168â€‹â€‹ 4,560,421â€‹â€‹$ 5,385,124â€‹$ 5,547,019â€‹Stock optionsThe following table summarizes all of the Companyâ€™s stock option activity for theÂ years ended SeptemberÂ 30, 2024:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Weightedâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Averageâ€‹â€‹â€‹â€‹â€‹â€‹Weightedâ€‹Remainingâ€‹â€‹â€‹â€‹â€‹Number ofâ€‹Averageâ€‹Contractualâ€‹Aggregateâ€‹Â Â Â Â SharesÂ Â Â Â Exercise PriceÂ Â Â Â Term (Years)Â Â Â Â Intrinsic ValueBalance at October 1, 2023â€‹ 1,197,774â€‹$ 28.72â€‹â€‹â€‹â€‹â€‹Grantedâ€‹ 817,729â€‹â€‹ 6.69â€‹â€‹â€‹â€‹â€‹Forfeitedâ€‹ (59,212)â€‹â€‹ 26.27â€‹â€‹â€‹â€‹â€‹Expiredâ€‹ (9,645)â€‹â€‹ 34.50â€‹â€‹â€‹â€‹â€‹Balance at SeptemberÂ 30,Â 2024â€‹ 1,946,646â€‹$ 19.51â€‹ 7.7â€‹$ 53,985Vested and exercisable at SeptemberÂ 30,Â 2024â€‹ 1,006,079â€‹$ 26.84â€‹ 6.5â€‹$ 53,985â€‹The aggregate intrinsic value represents the total amount by which the fair market value of the common stock subject to options exceeds the exercise price of the related options.The Company estimated the fair value of each stock option award on the grant date using the Black-Scholes option pricing model, wherein expected volatility is based on a weighted average of the Companyâ€™s historical volatility and the volatilities of similar entities within the Companyâ€™s industry which are commensurate with the expected term assumption. The expected term calculation is based on the â€œsimplifiedâ€ method described in Staff Accounting Bulletin (â€œSABâ€) No.Â 107, Share-Based Payment, and SAB No.Â 110, Share-Based Payment, since the simplified method provides a reasonable estimate in comparison to actual experience. The risk-free interest rate is based on the U.S. Treasury yield at the date of grant for an instrument with a maturity that is commensurate with the expected term of the stock options. The dividend yield is zero since the Company has never paid cash dividends on its common stock and has no present intention to pay cash dividends. Options granted under the 2024 Plan generally vest over one to four years and have a term of 10 years.124Table of ContentsThe weighted average grant date fair value of the options awarded to employees and directors for theÂ years ended SeptemberÂ 30, 2024 and 2023 was $6.04 and $19.40 per option, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹â€‹â€‹2024Â Â Â Â 2023â€‹Risk-free interest rateÂ Â Â Â 4.3%Â Â 3.7%Expected term (years)â€‹ 6.0â€‹ 5.9â€‹Expected volatilityâ€‹ 131.4%Â Â 111.6%Expected dividend yieldâ€‹ â€”â€‹ â€”â€‹â€‹As of SeptemberÂ 30, 2024, there was $7,508,106 of unrecognized compensation expense that is expected to be recognized over a weighted-average period of 1.3 years.Performance-based stock optionsThe Company granted certain officers of the Company option awards where vesting was contingent upon meeting certain company-wide performance goals. The performance stock options were granted â€œat-the-moneyâ€ and have a term of 10 years.The fair value of each option grant under the performance share option plan was estimated on the date of grant using the same option valuation model used for non-statutory options above. Compensation expense for performance-based stock options is only recognized when management determines it is probable that the awards will vest. The following table summarizes all of the Companyâ€™s performance-based stock option activity for the years ended September 30, 2024.â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Weightedâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Averageâ€‹â€‹â€‹â€‹â€‹â€‹Weightedâ€‹Remainingâ€‹â€‹â€‹â€‹â€‹Number ofâ€‹Averageâ€‹Contractualâ€‹Aggregateâ€‹Â Â Â Â SharesÂ Â Â Â Exercise PriceÂ Â Â Â Term (Years)Â Â Â Â Intrinsic ValueBalance at October 1, 2023â€‹ 35,000â€‹$ 28.80â€‹â€‹â€‹â€‹â€‹Grantedâ€‹ 634,000â€‹â€‹ 6.78â€‹â€‹â€‹â€‹â€‹Forfeitedâ€‹ (2,500)â€‹â€‹ 6.78â€‹â€‹â€‹â€‹â€‹Balance at SeptemberÂ 30,Â 2024â€‹ 666,500â€‹$ 7.94â€‹ 9.3â€‹$ â€”Vested and exercisable at SeptemberÂ 30,Â 2024â€‹ 35,000â€‹$ 28.80â€‹ 6.3â€‹$ â€”â€‹The weighted average grant date fair value of the performance stock options awarded for the years ended September 30, 2024 and 2023 was $6.52 and $18.20 per option, respectively. During the year ended September 30, 2024, no expense was recognized because the performance conditions were not considered probable of achievement. As of September 30, 2024, the Company assessed that the performance conditions related to the performance options granted were not probable of achievement. The assessment was based on the relevant facts and circumstances and therefore no compensation costs were recognized. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹â€‹Â Â Â Â 2024Â Â Â Â 2023â€‹Risk-free interest rateâ€‹ 4.3%Â Â 3.8%Expected term (years)â€‹ 10.0â€‹ 10.0â€‹Expected volatilityâ€‹ 125.6%Â Â 91.3%Expected dividend yieldâ€‹ â€”â€‹ â€”â€‹â€‹125Table of ContentsPerformance-based stock unitsThe Company has issued PSUs, which generally have a ten-year life from the date of grant. Upon exercise, the PSU holder receives common stock or cash at the Companyâ€™s discretion. The following table summarizes the activity related to PSUs during theÂ years ended SeptemberÂ 30, 2024:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Weightedâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Averageâ€‹â€‹â€‹â€‹â€‹Numberâ€‹Exercise â€‹Remainingâ€‹â€‹â€‹â€‹â€‹of â€‹Priceâ€‹Contractualâ€‹Aggregateâ€‹Â Â Â Â PSUsÂ Â Â Â Per PSUÂ Â Â Â Term (Years)Â Â Â Â Intrinsic ValueBalance at October 1, 2023â€‹ 123â€‹$ 999.40â€‹â€‹â€‹â€‹â€‹Expiredâ€‹ (123)â€‹â€‹ 999.40â€‹â€‹â€‹â€‹â€‹Balance at SeptemberÂ 30,Â 2024â€‹ â€”â€‹$ â€”â€‹ â€”â€‹$ â€”Vested and exercisable at SeptemberÂ 30,Â 2024â€‹ â€”â€‹$ â€”â€‹ â€”â€‹$ â€”â€‹â€‹â€‹12.Â Â Â Collaboration ArrangementsSyntone Strategic Partnership and PRC Joint VentureIn connection with a stock purchase agreement entered in May 2020 between the Company and Syntone, the Company and Syntone entered into a joint venture agreement pursuant to which they agreed to form a PRC joint venture that will be 80% owned by Syntone and 20% owned by the Company. Upon formation of the PRC joint venture in April 2021, the Company entered into a royalty-free license with the PRC joint venture for the development, commercialization and manufacture of ONS-5010/LYTENAVA in the greater China market, which includes Hong Kong, Taiwan and Macau.The Company made the initial investment of $900,000 in June 2020. The Company is committed to making up to $2,100,000 in additional capital contributions to the PRC joint venture, based upon the development plan contemplated in the license agreement or on such other terms.â€‹â€‹13.Â Â Â Income TaxesIncome tax benefit for theÂ years ended SeptemberÂ 30, 2024 and 2023 consists of the following:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â Â 2023State taxÂ $ 2,800Â $ 2,800â€‹A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â Â â€‹Â Â Â Â 2024Â Â Â Â 2023Â U.S. federal statutory rateâ€‹ (21.0)%Â Â (21.0)%State taxes, net of federal benefitÂ (6.2)Â (7.3)â€‹Deferred true-upâ€‹ 0.2â€‹ 0.1â€‹Permanent differencesÂ 2.5Â (0.7)â€‹Foreign tax creditsÂ 1.7Â 1.3â€‹Research and development creditÂ (2.4)Â (1.3)â€‹Change in valuation allowanceÂ 25.3Â 29.0â€‹OtherÂ (0.1)Â (0.1)â€‹Effective income tax rateÂ 0.0%Â Â 0.0%â€‹126Table of ContentsThe tax effects of the temporary differences that gave rise to deferred taxes were as follows:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹SeptemberÂ 30,Â â€‹Â Â Â Â 2024Â Â Â Â 2023Deferred tax assets:â€‹â€‹Â Â â€‹â€‹Â Â Net operating loss carryforwardsâ€‹$ 102,906,140â€‹$ 92,961,718Capitalized research and development costsâ€‹Â 15,200,918â€‹Â 6,531,508Stock-based compensationâ€‹Â 6,463,068â€‹Â 5,066,375Lease liabilityâ€‹â€‹ 83,720â€‹â€‹ â€”Research and development credit carryforwardâ€‹Â 13,748,600â€‹Â 11,953,956Foreign tax creditsâ€‹Â 290,188â€‹Â 1,562,639Accruals and othersâ€‹Â 144,079â€‹Â 1,656,239Gross deferred tax assetsâ€‹Â 138,836,713â€‹Â 119,732,435Less: valuation allowanceâ€‹Â (138,759,510)â€‹Â (119,725,078)â€‹â€‹Â 77,203â€‹Â 7,357Deferred tax liabilities:â€‹Â Â Â â€‹Â Â Â Property and equipmentâ€‹Â â€”â€‹Â â€”Right-of-use assetsâ€‹Â (77,203)â€‹Â (7,357)Net deferred tax assetsâ€‹$ â€”â€‹$ â€”â€‹As of September 30, 2024, the Company had approximately $406.7 million and $242.5 million of U.S. federal and New Jersey NOLs that will begin to expire in 2030 and 2039, respectively. As of September 30, 2024, the Company had federal and state research and development tax credit carryforwards of $13.0 million and $0.8 million, respectively, available to reduce future tax liabilities which will begin to expire in 2032 and 2033, respectively. As of September 30, 2024, the Company has federal foreign tax credit (â€œFTCâ€) carryforwards of $0.3 million available to reduce future tax liabilities which began to expire starting in 2023, of which $0.3 million of the FTC carryforward is included in the balance of unrecognized tax benefits. Realization of the deferred tax asset is contingent on future taxable income and based upon the level of historical losses, management has concluded that the deferred tax asset does not meet the more-likely-than-not threshold for realizability. Accordingly, a full valuation allowance continues to be recorded against the Companyâ€™s deferred tax assets as of September 30, 2024 and 2023. The valuation allowance increased by $19.0 million and $17.1 million during the year ended September 30, 2024 and 2023, respectively.When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely-than-not be realized. The determination as to whether the tax benefit will more-likely-than-not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company recognizes interest and penalties accrued on any unrecognized tax benefits within the provision for income taxes in its consolidated statements of operations.A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Year ended SeptemberÂ 30,Â â€‹â€‹2024â€‹2023Balance at beginning of yearÂ Â Â Â $ 1,856,629Â Â Â Â $ 1,856,629Changes based on tax positions related to the current yearâ€‹Â Â â€”â€‹Â â€”Balance at end of yearâ€‹$ 1,856,629â€‹$ 1,856,629â€‹The Company does not anticipate material change in the unrecognized tax benefits in the next 12Â months. These unrecognized tax benefits, if recognized, would affect the annual effective tax rate. The Companyâ€™s income tax returns for theÂ years from 2011 through 2023 remain open for examination by the Internal Revenue Service as well as various states and municipalities.Due to the change in ownership provisions of the Code, the availability of the Companyâ€™s NOL carryforwards may be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carryforwards. The Company has not analyzed the historical or potential impact of its equity financings 127Table of Contentson beneficial ownership and therefore no determination has been made whether the net operating loss carry forward is subject to any Code SectionÂ 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax assets with an offsetting reduction in the valuation allowance.â€‹14.Â Â Â Subsequent Eventsâ€‹Departure of Chief Executive OfficerOn December 3, 2024, C. Russell Trenary III stepped down as the President and Chief Executive Officer the Company and as a member of the Companyâ€™s Board of Directors (the â€œBoardâ€), effective immediately (the â€œEffective Dateâ€). The Board has resolved to reduce its size to nine directors immediately upon Mr. Trenaryâ€™s resignation.Mr. Trenaryâ€™s departure constituted a termination of employment without â€œcauseâ€ for purposes of any employment, equity compensation or benefit agreement, plan or arrangement of the Company and its subsidiaries to which Mr. Trenary is a party or otherwise participates, including that certain executive employment agreement, dated as of July 6, 2021, by and between Mr. Trenary and the Company (the â€œEmployment Agreementâ€). Accordingly, subject to Mr. Trenaryâ€™s execution and non-revocation of a separation agreement containing a release of claims against the Company, Mr. Trenary is entitled to continued payment of his base salary for 12 months following the termination, 100% of his target bonus for the calendar year of termination paid in a lump sum, employee benefit coverage for up to 12 months, full vesting of 50% of his then unvested equity awards, and reimbursement of expenses owed to him through the date of his termination. On December 3, 2024, Lawrence A. Kenyon, the Companyâ€™s Chief Financial Officer, was appointed Interim Chief Executive Officer of the Company, effective as of the Effective Date, to serve while the Board conducts a formal search process to identify and appoint a permanent Chief Executive Officer.Reduction in Workforce On December 10, 2024, the Board approved a reduction of the Companyâ€™s workforce in connection with its plans to reduce operating expenses and preserve capital. On December 13, 2024, the Company reduced its workforce by five people, or approximately 23% of its existing headcount. At a minimum, all employees affected by the workforce reduction are eligible to receive severance payments and paid COBRA premiums for a specified time period post-termination, subject to execution of a general release of claims against the Company. The Company estimates that it will incur approximately $336,000 in restructuring charges in connection with the workforce reduction, consisting of cash-based expenses related to employee severance and notice period payments, benefits and related costs.128Table of Contentsâ€‹Item 9. Changes in and Disagreements with Accountants on Accounting and Financial DisclosureNone.Item 9A. Controls and ProceduresEvaluation of Disclosure Controls and ProceduresOur management, with the participation of our Interim Chief Executive Officer and Chief Financial Officer, has evaluated 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, or the Exchange Act) prior to the filing of this Annual Report on Form 10-K. Based on that evaluation, our Interim Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were, in design and operation, effective as of September 30, 2024.Internal Control over Financial ReportingOur management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control-Integrated Framework. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of September 30, 2024.As a smaller reporting company, our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting.Changes in Internal Control over Financial ReportingThere were no changes in our internal control over financial reporting during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.Inherent Limitation on the Effectiveness of Internal Control.The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate

for our business but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.Item 9B. Other InformationDuring the fiscal year covered by this Annual Report, none of our directors or Section 16 officers adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative 129Table of Contentsdefense conditions of Rule 10b5-1(c) under the Exchange Act or any â€œnon-Rule 10b5-1 trading arrangementâ€ as such term is defined in Item 408(a) of Regulation S-K.â€‹Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections. Not applicable.130Table of ContentsPART IIICertain information required by Part III is omitted from this Report on Form 10-K because we intend to file our definitive Proxy Statement for our next Annual Meeting of the Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, or the 2025 Proxy Statement, no later than January 28, 2025, and certain information to be included in the 2025 Proxy Statement is incorporated herein by reference.Item 10. Directors, Executive Officers and Corporate GovernanceThe information required by this item is to be included in our 2025 Proxy Statement as follows: Â·The information relating to our directors and nominees for director is to be included in the section entitled â€œElection of Directorsâ€; Â·The information relating to our executive officers is to be included in the section entitled â€œExecutive Officers of the Companyâ€; Â·If required, the information regarding compliance with Section 16(a) of the Exchange Act is to be included in the section entitled â€œDelinquent Section 16(a) Reportsâ€; Â Â·The information regarding family relationships is to be included in the section entitled â€œElection of Directors â€” Family Relationshipsâ€; Â·The information relating to our audit committee and audit committee financial expert is to be included in the section entitled â€œInformation Regarding the Board of Directors and Corporate Governance â€” Audit Committeeâ€.â€‹We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Business Conduct and Ethics is publicly available on our website under the Investors & Media section at ir.outlooktherapeutics.com. This website address is intended to be an inactive, textual reference only; none of the material on this website is part of this Annual Report on Form 10-K. We intend to promptly disclose on our website or in a Current Report on Form 8-K in the future (i) the date and nature of any amendment (other than technical, administrative or other non-substantive amendments) to the Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Conduct that is granted to one of these specified individuals that relates to one or more of the elements of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, the name of such person who is granted the waiver and the date of the waiver.â€‹We have adopted an Insider Trading Policy governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees and by us. A copy of the Insider Trading Policy is filed as an exhibit to this Annual Report on Form 10-K.â€‹Item 11. Executive CompensationThe information required by this item is to be included in our 2025 Proxy Statement under the section entitled â€œExecutive Compensationâ€ and is incorporated herein by reference, provided that if the 2025 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.â€‹131Table of ContentsItem 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder MattersThe information required with respect to equity compensation plans is to be included in our 2025 Proxy Statement under the section entitled â€œEquity Compensation Plan Informationâ€ and the information required by this item with respect to security ownership of certain beneficial owners and management is to be included in our 2025 Proxy Statement under the section entitled â€œSecurity Ownership of Certain Beneficial Owners and Managementâ€ and is incorporated herein by reference, provided that if the 2025 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period. Item 13. Certain Relationships and Related Transactions, and Director IndependenceThe information required by this item is to be included in our 2025 Proxy Statement under the sections entitled â€œTransactions with Related Personsâ€ and â€œInformation Regarding the Board of Directors and Corporate Governance â€” Independence of the Board of Directorsâ€ and is incorporated herein by reference, provided that if the 2025 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.Item 14. Principal Accounting Fees and ServicesThe information required by this item is to be included in our 2025 Proxy Statement under the section entitled â€œRatification of Selection of Independent Registered Public Accounting Firmâ€ and is incorporated herein by reference, provided that if the 2025 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.â€‹132Table of ContentsPART IVItem 15. Exhibits and Financial Statement Schedules(a)Â Â Â (1)Â Â Â The financial statements required by Item 15(a) are filed in Item 8 of this Annual Report on Form 10-K.(2)Â Â Â The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.â€‹EXHIBITSâ€‹â€‹Exhibitâ€‹NumberÂ Â Â Description3.1Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrantâ€™s quarterly report on Form 10-Q filed with the SEC on May 15, 2024).â€‹â€‹3.2â€‹Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrantâ€™s current report on Form 8-K filed with the SEC on March 26, 2021).â€‹â€‹4.1â€‹Description of Registrantâ€™s securities.â€‹â€‹10.1#2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrantâ€™s registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).â€‹â€‹10.2#Form of Amended and Restated Performance Stock Unit Agreement for 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Registrantâ€™s registration statement on Form S-1 (File No. 333-209011) filed with the SEC on April 27, 2016).â€‹â€‹10.3#2015 Equity Incentive Plan, as amended and restated (incorporated by reference to Exhibit 99.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on September 18, 2020).â€‹â€‹10.4#Forms of agreements and award grant notices for 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrantâ€™s registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).â€‹â€‹10.5#â€‹2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Registrantâ€™s quarterly report on Form 10-Q filed with the SEC on August 14, 2024).â€‹â€‹10.6#â€‹Form of Stock Option Grant Notice and Stock Option Agreement under the 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to Registrantâ€™s quarterly report on Form 10-Q filed with the SEC on August 14, 2024). â€‹â€‹10.7#2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Registrantâ€™s registration statement on Form S-1 (File No. 333-209011) filed with the SEC on February 12, 2016).â€‹â€‹10.8#â€‹Executive Employment Agreement by and between C. Russell Trenary III and Outlook Therapeutics, Inc, dated July 6, 2021 (incorporated by reference to Exhibit 10.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on July 9, 2021).â€‹â€‹10.9#â€‹Amended and Restated Executive Employment Agreement by and between Lawrence Kenyon and Outlook Therapeutics, Inc, dated June 2, 2022 (incorporated by reference to Exhibit 10.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on June 7, 2022).â€‹â€‹133Table of Contents10.10#â€‹Executive Employment Agreement by and between Jeff Evanson and Outlook Therapeutics, Inc, dated December 21, 2021 (incorporated by reference to Exhibit 10.2 to the Registrantâ€™s current report on Form 8-K filed with the SEC on December 23, 2021).â€‹â€‹10.11#â€‹Outlook Therapeutics, Inc. Non-Employee Director Compensation Policy, as amended and restated, effective as of October 1, 2024.â€‹â€‹10.12#Form of Indemnity Agreement, by and between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.12 to the Registrantâ€™s registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).â€‹â€‹10.13â€ â€‹ONS-1045 Commercial License Agreement by and between the Registrant and Selexis SA effective as of April 11, 2013, as amended effective as of May 21, 2014 (incorporated by reference to Exhibit 10.15 to the Registrantâ€™s registration statement on Form S-1 (File No. 333-209011) filed with the SEC on January 15, 2016).â€‹â€‹10.14Amended and Restated Investor Rights Agreement by and between the Registrant and GMS Ventures and Investments, dated April 21, 2022 (incorporated by reference to Exhibit 10.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on April 22, 2022).â€‹â€‹10.15â€‹Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on February 24, 2020). Â â€‹â€‹10.16â€‹Form of GMS Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the Registrantâ€™s current report on Form 8-K filed with the SEC on February 24, 2020).â€‹â€‹10.17â€‹Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Registrantâ€™s current report on Form 8-K filed with the SEC on February 24, 2020).â€‹â€‹10.18â€‹Stock Purchase Agreement dated May 22, 2020, by and between the Registrant and Syntone Ventures LLC (incorporated by reference to Exhibit 10.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on May 28, 2020). â€‹â€‹10.19Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on June 23, 2020). â€‹â€‹10.20â€‹Form of underwriter warrant (incorporated by reference to Exhibit 4.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on February 2, 2021).â€‹â€‹10.21**â€‹Securities Purchase Agreement, dated as of December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on December 22, 2022).â€‹â€‹10.22â€‹Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.2 to the Registrantâ€™s current report on Form 8-K filed with the SEC on December 22, 2022).â€‹â€‹10.23â€‹Amendment, dated February 10, 2023, to the Convertible Promissory Note, dated December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrantâ€™s quarterly report on Form 10-Q filed with the SEC on February 14, 2023).â€‹â€‹10.24â€‹Amendment, dated December 21, 2023, to the Convertible Promissory Note, dated December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.30 to Registrantâ€™s annual report on Form 10-K filed with the SEC on December 22, 2023).â€‹â€‹134Table of Contents10.25â€‹Third Amendment, dated January 22, 2024, to the Convertible Promissory Note, dated December 22, 2022, by and between the Company and Streeterville Capital, LLC (incorporated by reference to Exhibit 10.6 to the Registrantâ€™s current report on Form 8-K filed with the SEC on January 24, 2024).â€‹â€‹10.26â€‹Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on December 23, 2022).â€‹â€‹10.27â€‹At-the-market Sales Agreement between the Company and BTIG, LLC dated May 16, 2023 (incorporated by reference to Exhibit 10.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on May 16, 2023).â€‹â€‹10.28â€‹Form of Registration Rights Agreement, dated January 22, 2024, between the Company and the investors party thereto (incorporated by reference to Exhibit 10.3 to the Registrantâ€™s current report on Form 8-K filed with the SEC on January 24, 2024).â€‹â€‹10.29â€‹Registration Rights Agreement, dated January 22, 2024, between the Company and Syntone (incorporated by reference to Exhibit 10.5 to the Registrantâ€™s current report on Form 8-K filed with the SEC on January 24, 2024).â€‹â€‹10.30â€‹Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on January 24, 2024).â€‹â€‹10.31â€‹Form of Syntone Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the Registrantâ€™s current report on Form 8-K filed with the SEC on January 24, 2024).â€‹â€‹10.32â€‹Amendment, dated April 12, 2024, to Sales Agreement, dated May 16, 2023, by and between the Company and BTIG (incorporated by reference to Exhibit 10.1 to the Registrantâ€™s current report on Form 8-K filed with the SEC on April 12, 2024).â€‹â€‹19.1â€‹Insider Trading Policy, as amended and restated.â€‹â€‹21.1â€‹Subsidiaries of the Registrant.â€‹â€‹23.1Consent of independent registered public accounting firm.â€‹â€‹31.1Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.â€‹â€‹32.1*Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.â€‹â€‹97â€‹Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97 to the Registrantâ€™s annual report on Form 10-K filed with the SEC on December 22, 2023).â€‹â€‹101.INSInline XBRL Instance Documentâ€‹â€‹101.SCH Inline XBRL Taxonomy Extension Schema Documentâ€‹â€‹101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase Documentâ€‹â€‹101.DEF Inline XBRL Definition Linkbase Documentâ€‹â€‹101.LAB Inline XBRL Taxonomy Extension Labels Linkbase Document135Table of Contentsâ€‹â€‹101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Documentâ€‹â€‹104â€‹Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)â€‹ Confidential treatment has been granted for certain information contained in this document pursuant to an order of the SEC. Such information (indicated by asterisks) has been omitted and been filed separately with the SEC.Â¥Certain portions of this exhibit (indicated by â€œ[***]â€) have been omitted because they are not material.*Furnished herewith and not deemed to be â€œfiledâ€ for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.#Indicates management contract or compensatory plan.**Certain of the exhibits and schedules to this exhibit 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 Securities and Exchange Commission upon its request.â€‹â€‹Item 16. Form 10-K SummaryNone.â€‹136Table of ContentsSIGNATURESPursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.â€‹Date: December 27, 2024By: /s/ Lawrence A. KenyonName:Lawrence A. KenyonTitle:Chief Financial Officer and Interim Chief Executive Officerâ€‹SIGNATURESPursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.â€‹/s/ Ralph H. ThurmanÂ Â Â Â Executive ChairmanÂ Â Â Â December 27, 2024Ralph H. Thurmanâ€‹â€‹Chief Financial Officer, Interim Chief Executive Officer,â€‹/s/ Lawrence A. Kenyonâ€‹Treasurer, Secretary and Directorâ€‹December 27, 2024Lawrence A. Kenyonâ€‹(Principal Executive, Financial and Accounting Officer)â€‹â€‹/s/ Yezan Haddadinâ€‹Directorâ€‹December 27 2024Yezan Haddadinâ€‹â€‹/s/ Kurt J. Hilzingerâ€‹Directorâ€‹December 27, 2024Kurt J. Hilzingerâ€‹â€‹/s/ Julia A. Hallerâ€‹Directorâ€‹December 27, 2024Julia A. Hallerâ€‹â€‹/s/ Faisal G. Sukhtianâ€‹Directorâ€‹December 27, 2024Faisal G. Sukhtianâ€‹â€‹/s/ Julian Gangolliâ€‹Directorâ€‹December 27, 2024Julian Gangolliâ€‹â€‹/s/ Gerd Auffarthâ€‹Directorâ€‹December 27, 2024Gerd Auffarthâ€‹â€‹/s/ Andong Huangâ€‹Directorâ€‹December 27, 2024Andong Huangâ€‹â€‹137Exhibit 4.1â€‹Description of Registrantâ€™s SecuritiesThe following is a description of the capital stock of Outlook Therapeutics, Inc. (the â€œCompany,â€ â€œwe,â€ â€œour,â€ or â€œusâ€). The following summary description is based on the provisions of our Amended and Restated Certificate of Incorporation, as amended (the â€œCertificate of Incorporationâ€), our Amended and Restated Bylaws, (the â€œBylawsâ€), and the applicable provisions of the Delaware General Corporation Law (the â€œDGCLâ€). This information may not be complete in all respects and is qualified entirely by reference to the provisions of our Certificate of Incorporation, our Bylaws and the DGCL. Our Certificate of Incorporation and our Bylaws are filed as exhibits to our Annual Report on Form 10-K to which this description is filed as Exhibit 4.1.â€‹Generalâ€‹Our authorized capital stock consists of 60,000,000 shares of common stock, par value $0.01 per share (the â€œCommon Stockâ€), and 10,000,000 shares of preferred stock, par value $0.01 per share (the â€œPreferred Stockâ€).â€‹Common Stockâ€‹Voting Rightsâ€‹Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of 66 2â„•3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our Certificate of Incorporation, including provisions relating to amending our Bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.â€‹Dividendsâ€‹Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.â€‹Liquidationâ€‹In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any outstanding preferred stock.â€‹Rights and Preferencesâ€‹Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.â€‹Preferred Stockâ€‹Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the number, rights, preferences, privileges and restrictions thereof.â€‹These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of

holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control or other corporate action. â€‹Stockholder Registration Rightsâ€‹Certain holders of our securities, including certain holders of 5% of our capital stock who are affiliated with certain of our directors, are entitled to certain rights with respect to registration of such securities under the Securities Act of 1933, as amended. These securities are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of registration rights agreements. In general, the registration of shares of our common stock pursuant to the exercise of registration rights enables the holders to trade such shares without restriction under the Securities Act when the applicable registration statement is declared effective. We generally have agreed to pay the registration expenses for such registration statements, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered. Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares the holders may include. We must use commercially reasonable efforts to keep the registration statement effective until the earlier of the date on which all registrable securities covered by such registration statement have been sold, or at such time that the holders of the registrable securities can sell their shares under Rule 144 of the Securities Act during any three-month period.â€‹Anti-Takeover Provisions of Delaware Law and Our Charter Documentsâ€‹Section 203 of the DGCLâ€‹We are subject to Section 203 of the DCGL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:â€‹â—before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;â€‹â—upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; andâ€‹â—on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2â„•3% of the outstanding voting stock that is not owned by the interested stockholder.â€‹In general, Section 203 defines a â€œbusiness combinationâ€ to include the following:â€‹â—any merger or consolidation involving the corporation and the interested stockholder; any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder; subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;â€‹â—any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder;â€‹â—the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation; andâ€‹â—in general, Section 203 defines an â€œinterested stockholderâ€ as an entity or person who, together with the personâ€™s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.â€‹The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.â€‹Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as Amendedâ€‹Among other things, our Certificate of Incorporation and Bylaws:â€‹â—permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;â€‹â—provide that the authorized number of directors may be changed only by resolution of our board of directors;â€‹â—provide that our board of directors is classified into three classes of directors;â€‹â—provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected, subject to any limitation imposed by law, by the holders of at least a majority of the voting power of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;â€‹â—provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;â€‹â—require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;â€‹â—provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholderâ€™s notice;â€‹â—provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or president or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; andâ€‹â—not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.â€‹The amendment of any of these provisions requires approval by the holders of at least 66 2â„•3% of the voting power of all of our then-outstanding common stock entitled to vote generally in the election of directors, voting together as a single class.â€‹The combination of these provisions may make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.â€‹These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.â€‹Choice of Forumâ€‹Our Certificate of Incorporation and our Bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty to us or our stockholders; any action asserting a claim against us arising pursuant to any provision of the DGCL, our Certificate of Incorporation or our Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.â€‹The enforceability of similar choice of forum provisions in other companiesâ€™ certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable.â€‹Listingâ€‹Our common stock is listed on The Nasdaq Capital Market under the symbol â€œOTLKâ€.â€‹Transfer Agent and Registrarâ€‹The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. Its address is 48 Wall Street, Floor 23, New York, NY 10005.â€‹Exhibit 10.11â€‹OUTLOOK THERAPEUTICS, INC.NON-EMPLOYEE DIRECTOR COMPENSATION POLICYAS AMENDED AND RESTATED EFFECTIVE OCTOBER 1, 2024Each member of the Board of Directors (the â€œBoardâ€) who is not also serving as an employee of Outlook Therapeutics, Inc. (the â€œCompanyâ€) or any of its subsidiaries (each such member, an â€œEligible Directorâ€) will receive the compensation described in this Non-Employee Director Compensation Policy (the â€œPolicyâ€) for his or her Board service with respect to the Companyâ€™s fiscal year beginning on October 1 (each, a â€œFiscal Yearâ€). This Non-Employee Director Compensation Policy, as amended and restated hereby, will be effective as of October 1, 2024 (the â€œEffective Dateâ€). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. Â This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board (the â€œCommitteeâ€). Â The terms and conditions of this Policy shall supersede any prior Non-Employee Director Compensation Policy of the Company.Annual Cash CompensationEligible Directors are eligible to receive the following annual cash compensation in the amounts and subject to the terms and conditions as set forth below. Â If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment. Â In addition, each Eligible Director may elect to receive all of the annual cash compensation set forth below that the Eligible Director is eligible to earn beginning with the Fiscal Year commencing on October 1, 2024 and each subsequent Fiscal Year in the form of stock options granted pursuant to the Companyâ€™s 2024 Equity Incentive Plan, as amended (the â€œPlanâ€) subject to the terms and conditions as set forth below.1.Annual Board Service Retainers:a.All Eligible Directors: $50,000b.Chairman of the Board Service Retainer (in addition to Annual Board Service Retainer): $30,000c.Executive Chairman of the Board Service Retainer (in addition to Annual Board Service Retainer): $120,0002.Annual Committee Member Service Retainer:a.Member of the Audit Committee: $12,500b.Member of the Compensation Committee: $10,000c.Member of the Nominating and Corporate Governance Committee: $5,000d.Member of the Executive Committee: $30,000â€‹1.â€‹â€‹3.Annual Committee Chair Service Retainer (in lieu of Annual Committee Member Service Retainer):a.Chairman of the Audit Committee: $25,000b.Chairman of the Compensation Committee: $20,000c.Chairman of the Nominating and Corporate Governance Committee: $10,000Timing of Elections Regarding Annual Cash Compensation; Time and Form of Payment1.Current Eligible Directors: If an Eligible Directorâ€™s service as an Eligible Director commences prior to the beginning of a Fiscal Year, then the Eligible Director must make an election, prior to the beginning of such Fiscal Year, to receive the Eligible Directorâ€™s (i) Annual Board Service Retainer(s) for such Fiscal Year and (ii) any Annual Committee Member Service Retainer(s) or Annual Committee Chair Service Retainer(s) that is or may become payable for such Fiscal Year (each, a â€œRetainerâ€) in the form of either cash or stock options. Â The Retainer(s) will be paid or granted as follows:Â·Cash: If the Eligible Director elects to receive all or a portion of the Retainers in cash, (i) such portion of the Retainers that is payable in the form of cash, other than the Executive Chairman of the Board Service Retainer, will be paid in arrears in substantially equal installments over the applicable number of fiscal quarters during such Fiscal Year, with payment occurring on the last day of the applicable fiscal quarter (i.e., December 31st, March 31st, June 30th or September 30th), and (ii) the Executive Chairman of the Board Service Retainer will be paid in the form of cash in arrears in equal monthly installments on the last day of each month.Â·Stock Options: If the Eligible Director elects to receive all or a portion of the Retainers in the form of stock options, such portion of the Retainers that is payable in the form of stock options will automatically, and without further action by the Board or Committee of the Board, be granted on the third business day in October of such Fiscal Year. Â Any such award will vest as follows: (i) 25% will vest on the last day of the first fiscal quarter during such Fiscal Year; and (ii) 25% will vest on the last day of each subsequent fiscal quarter during such Fiscal Year, provided that the Eligible Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date. Â Notwithstanding the foregoing, if the Eligible Director becomes a chairperson of a Committee, Chairman of the Board or Executive Chairman of the Board after the third business day in October of such Fiscal Year, then the portion (if any) of his or her Annual Committee Chair Service Retainer, Chairman of the Board Service Retainer or Executive Chairman of the Board Service Retainer, as applicable, that is to be granted in the form of stock options will automatically, and without further action by the Board or Committee of the Board, Â be granted on the third business day after the date that the Eligible Director becomes a chairperson of a Committee, Chairman of the Board or Executive Chairman of the Board, as applicable. Â Any such award will vest in equal installments as follows: (i) the first installment will vest on the last day of the fiscal quarter of the date of grant; and (ii) any remaining installment(s) will vest on the last day of any subsequent fiscal quarter(s) during such Fiscal Year,â€‹2.â€‹â€‹provided that the Eligible Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date.2.New Eligible Directors: If an Eligible Directorâ€™s service as an Eligible Director commences on or after the beginning of a Fiscal Year, then the Eligible Director must make an election, within 30 days following the commencement of such service, with respect to his or her Retainers that are or may become payable for such Fiscal Year; provided, however, that (a) such election will be applicable only to the portion of the applicable Retainer payable for any fiscal quarter during such Fiscal Year that begins after the date of such election, and (b) no such election may be made if such service commences during the final fiscal quarter of such Fiscal Year. Â Each such Retainer will be paid or granted as follows:Â·Cash: Â If the Eligible Director elects to receive all or a portion of the Retainers in cash, (i) any portion of the Retainers that is payable in the form of cash, other than the Executive Chairman of the Board Service Retainer, with respect to any fiscal quarter during such Â Fiscal Year that begins after the date of such election will be paid in substantially equal installments over the applicable number of fiscal quarters during such Fiscal Year, with payment occurring on the last day of the applicable fiscal quarter, and (ii) the Executive Chairman of the Board Service Retainer with respect to the remaining portion of the Fiscal Year that begins after the date of such election will be paid in the form of cash in arrears in equal monthly installments on the last day of each month.Â·Stock Options: Â If the Eligible Director elects to receive all or a portion of the Retainers in the form of stock options, with respect to any fiscal quarter (or month with respect to the Executive Chairman of the Board Service Retainer) during such Fiscal Year that begins after the date of such election, such stock options will automatically, and without further action by the Board or Committee of the Board, be granted on the first business day of the first fiscal quarter that begins after the date of such election. Â Any such award will vest in equal installments as follows: (i) the first installment will vest on the last day of the fiscal quarter of the date of grant; and (ii) any remaining installment(s) will vest on the last day of any subsequent fiscal quarter(s) during such Fiscal Year, provided that the Eligible Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date. Â Notwithstanding the foregoing, if the Eligible Director becomes a chairperson of a Committee, Chairman of the Board or Executive Chairman of the Board after the first business day of the first fiscal quarter that begins after the date of such election, then the portion (if any) of his or her Annual Committee Chair Service Retainer, Chairman of the Board Service Retainer or Executive Chairman of the Board Service Retainer, as applicable, that is to be granted in the form of stock options, will automatically, and without further action by the Board or Committee of the Board, be granted on the third business day after the date that the Eligible Director becomes a chairperson of a Committee, Chairman of the Board or Executive Chairman of the Board, as applicable. Â Any such award will vest in equal installments as follows: (i) the first installment will vest on the last day of the fiscal quarter of the date of grant; and (ii) any remaining installment(s) will vest on the last day of any subsequent fiscal quarter(s) during such Fiscal Year, provided that theâ€‹3.â€‹â€‹Eligible Director is in service as a Director on the first day of the fiscal quarter of the applicable scheduled vesting date.Terms of Elections Regarding Annual Cash Compensation:Â·Once an election is submitted for a Fiscal Year, it will be irrevocable with respect to such Fiscal Year.Â·An Eligible Director must submit a new election for each Fiscal Year.Â·Elections with respect to an Eligible Directorâ€™s Retainers must be allocated in either cash or stock options as follows: (i) 0% in cash and 100% in stock options; (ii) 50% in cash and 50% in stock options; and (iii) 100% in cash and 0% in stock options. Â To the extent that an Eligible Director elects to receive such Eligible Directorâ€™s Retainers partially in cash and partially in stock options, the election will apply proportionally, in accordance with the elected amounts of cash and stock options, with respect to each installment of the Retainers during the applicable period. An Eligible Director may not make an election to receive cash or stock options with respect to an individual Retainer.Terms of Stock Options Granted Pursuant to Elections:Â·Any stock options granted pursuant to an Eligible Directorâ€™s election will be granted under the Plan and will be subject to the terms and conditions of (i) this Policy, (ii) the Plan and (iii) the form stock option grant notices and agreements approved by the Board for the grant of such awards to Non-Employee Directors (as defined in the Plan).Â·The actual number of shares subject to any stock options granted pursuant to this Policy and an Eligible Directorâ€™s election to receive all or a portion of the Retainers in the form of stock options will be determined by dividing the Retainers by the â€œfair valueâ€ of a share of the Companyâ€™s common stock (â€œCommon Stockâ€) on the third business day in October of the Fiscal Year in which the stock option is granted, determined using a Black-Scholes or binominal valuation model regularly used by the Company.Â·The shares subject to any stock options granted pursuant to an Eligible Directorâ€™s election will vest in installments subject to the Eligible Directorâ€™s Continuous Service (as defined in the Plan) through such vesting dates on the terms specified above; provided, however, that all unvested shares subject to such stock options will accelerate and vest in full upon a Change in Control (as defined in the Plan), subject in each case to the Eligible Directorâ€™s Continuous Service as of immediately prior to the Change in Control.Â·Any stock options granted pursuant to this Policy will be nonqualified stock options, will have an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the Common Stock on the date of grant and will have a term of ten years

from the date of grant (subject to earlier termination in connection with the Eligible Directorâ€™s termination of service or certain corporate transactions and in accordance with the terms of the Plan). Â Any such stock option will become exercisable when vested and the vested portion of any such stock optionâ€‹.â€‹â€‹will remain exercisable in accordance with the stock option grant notice and agreement governing the stock option.Equity CompensationThe equity compensation set forth below will be granted under the Plan, and will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).1.Initial Grant: On the date of the Eligible Directorâ€™s initial election to the Board, for each Eligible Director who is first elected to the Board following the Effective Date (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase shares of Common Stock with an aggregate â€œfair valueâ€ of $245,000, determined using a Black-Scholes or binominal valuation model regularly used by the Company. Â The shares subject to each such stock option will vest in three equal installments on the first, second and third anniversary of the date of grant (with the first two tranches rounded down and the third tranche rounded up to the nearest share) such that the stock option will be fully vested as of the third anniversary of the date of grant, subject to the Eligible Directorâ€™s Continuous Service through such vesting dates, provided, however, that all unvested shares subject to such stock options will accelerate and vest in full upon a Change in Control, subject in each case to the Eligible Directorâ€™s Continuous Service as of immediately prior to the Change in Control.2.Annual Grant: On the first day of each fiscal year of the Company commencing with the 2025 fiscal year (i.e., beginning on the Effective Date), each Eligible Director who is then serving as a non-employee member of the Board will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase Common Stock with an aggregate â€œfair valueâ€ of $265,000 as of such date, determined using a Black-Scholes or binominal valuation model regularly used by the Company. Â The shares subject to each such stock option will vest on the first anniversary of the date of grant, subject in each case to the Eligible Directorâ€™s Continuous Service through such vesting date, provided, however, that all unvested shares subject to such stock options will accelerate and vest in full upon a Change in Control, subject in each case to the Eligible Directorâ€™s Continuous Service as of immediately prior to the Change in Control.Non-Employee Director Compensation LimitNotwithstanding anything herein to the contrary, the aggregate value of all compensation granted or paid, as applicable, to an Eligible Director shall in no event exceed the limits set forth in Section 3(d) of the Plan.5.â€‹â€‹Exhibit 19.1OUTLOOK THERAPEUTICS, INC.AMENDED AND RESTATEDINSIDER TRADING POLICYInitially Adopted by the Board - January 28, 2016As Amended and Restated by the Board â€“ June 21, 2023As Amended and Restated by the Board â€“ December 10, 2024I. Â INTRODUCTIONThis policy determines acceptable transactions in the securities of Outlook Therapeutics, Inc. (the â€œCompanyâ€ or â€œOutlookâ€) by our employees, directors, consultants and contractors. During the course of your relationship with the Company, you may receive important information that is not yet publicly available (â€œinside informationâ€), about the Company or about other publicly traded companies with which the Company has business dealings. Â Because of your access to this inside information, you may be in a position to profit financially by buying or selling, or in some other way dealing, in the Companyâ€™s stock, or stock of another publicly traded company, or to disclose such information to a third party who does so profit (a â€œtippeeâ€).The prohibition against insider trading is absolute. It applies even if the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions and bona fide gifts. All that matters is whether you are aware of any material nonpublic information relating to the Company at the time of the transaction. The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve the Companyâ€™s reputation for adhering to the highest standards of conduct.II. INSIDER TRADING POLICYA. Securities TransactionsUse of inside information by someone for personal gain, or to pass on, or â€œtip,â€ the inside information to someone who uses it for personal gain, is illegal, regardless of the quantity of shares, and is therefore prohibited. Â You can be held liable both for your own transactions and for transactions effected by a tippee, or even a tippee of a tippee. Â Furthermore, it is important that the appearance of insider trading in securities be avoided. Â There are no exceptions to this policy, except as specifically noted below.B. Inside InformationAs a practical matter, it is sometimes difficult to determine whether you possess inside information. Â The key to determining whether nonpublic information you possess about a public company is inside information is whether dissemination of the information would likely affect the market price of the companyâ€™s stock or would likely be considered important, or â€œmaterial,â€ by investors who are considering trading in that companyâ€™s stock. Â Certainly, if the information makes you want to trade, it would probably have the same effect on others. Â Remember, both positive and negative information can be material. Â If you possess inside information, you may not trade in a companyâ€™s stock, advise anyone else to do so or communicate the information to anyone else until you know that the information has been publicly disseminated. This policy also applies to all family members and other household members of1.â€‹those covered by this policy and all companies controlled by those covered by this policy. You may never recommend to another person that he or she buy, hold, sell or otherwise acquire or dispose of our securities. This means that in some circumstances, you may have to forego a proposed transaction in a companyâ€™s securities even if you planned to execute the transaction prior to learning of the inside information and even though you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting. Â For purposes of this policy, the terms â€œtrade,â€ â€œtradingâ€ and â€œtransactionsâ€ include not only purchases and sales of the Companyâ€™s common stock in the public market but also any other purchases, sales, transfers, gifts or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.You may not participate in â€œchat roomsâ€ or other electronic discussion groups or contribute to blogs, bulletin boards or social media forums on the Internet concerning the activities of the Company or other companies with which the Company does business, even if you do so anonymously, unless doing so is part of your job responsibilities and you have explicit authorization from the Compliance Officer (the Chief Financial Officer of the Company).Although by no means an all-inclusive list, information about the following items may be considered to be inside information until it is publicly disseminated:(a)financial results or forecasts;(b)major new products or processes;(c)communications with government agencies, such as the FDA;(d)strategic plans;(e)discovery and development of new product candidates and new technology;(f)details, including timelines, or results of clinical trials of the Company's product candidates;(g)significant changes or developments in suppliers;(h)major new drugs, processes or services, or many developments related to the same;(i)acquisitions or dispositions of assets, divisions, companies, etc.;(j)pending public or private sales of debt or equity securities;(k)declaration of stock splits, dividends or changes in dividend policy;(l)major contract awards or cancellations;(m)scientific, clinical. legislative or regulatory results or developments;(n)key management or control changes;(o)possible tender offers or proxy fights;â€‹2.â€‹(p)employee layoffs;(q)financial restatements or significant writeoffs;(r)the establishment of a repurchase program with respect to the Companyâ€™s securities;(s)actual or threatened significant litigation, or the resolution of such litigation;(t)impending bankruptcy of the Company or its key collaborators or partners;(u)gain or loss of a significant license agreement or other contracts with customers or suppliers;(v)pricing changes or discount policies;(w)a disruption in the Companyâ€™s operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;(x)establishment of or developments related to corporate partner relationships, strategic partnerships, joint ventures or other collaborations; and(y)notice of issuance or denial of patents.For information to be considered publicly disseminated, it must be widely disclosed through a press release or U.S. Securities and Exchange Commission (the â€œSECâ€) filing, and a sufficient amount of time must have passed to allow the information to be fully disclosed. Â Generally speaking, information will be considered publicly disseminated after two full trading days have elapsed since the date of public disclosure of the information. Â For example, if an announcement of inside information of which you were aware was made prior to trading on Wednesday, then you may execute a transaction in the Companyâ€™s securities on Friday.III. STOCK TRADING BY OFFICERS, DIRECTORS AND OTHER EMPLOYEESBecause the officers and directors and certain members of management of the Company are the most visible to the public and are most likely, in the view of the public, to possess inside information about the Company, we require them to do more than refrain from insider trading. Â We require that they limit their transactions in the Companyâ€™s stock to defined time periods following public dissemination of quarterly and annual financial results and notify, and receive approval from the Compliance Officer prior to engaging in transactions in the Companyâ€™s stock and observe other restrictions designed to minimize the risk of apparent or actual insider trading. We also require that employees limit their transactions in the Companyâ€™s stock to defined time periods following public dissemination of quarterly and annual financial results.A. Covered InsidersThe provisions outlined in this stock trading policy apply to all officers, directors, employees and consultants of the Company. Generally, any entities or immediate family members or others whose trading activities are controlled by any of such persons should be considered to be subject to the same restrictions.â€‹3.â€‹B. Window PeriodGenerally, except as set forth in this policy, officers, directors and employees may buy or sell securities of the Company only during an open â€œwindow periodâ€ that opens after two full trading days have elapsed after the public dissemination of the Companyâ€™s annual or quarterly financial results and closes after the close of the trading on the last trading day of the quarter or year, as applicable. This window period may be closed and may not reopen if, in the judgment of the Companyâ€™s Chief Executive Officer or Chief Financial Officer, there exists undisclosed information that would make trades inappropriate. This closing of the window period/prohibition on trading is commonly called, and referred to in this policy, as a â€œtrading blackout.â€ A trading blackout may be implemented, for example, if there is some information or development with or relating to the Companyâ€™s business that merits a suspension of trading. Â It is important to note that the fact that a trading blackout has been imposed and/or that the window period has not reopened should be considered inside information. Â If a trading blackout has been imposed due to the existence of material nonpublic information, generally the window period will not re-open until the third trading day (e.g., two full trading days have elapsed) after the Companyâ€™s public dissemination of the material nonpublic information, or until such time a determination is made that it is no longer material nonpublic information. Â An officer, director or other employee who believes that special circumstances require him or her to trade outside the window period (e.g., during any trading blackout period) should consult with the Compliance Officer who will consult with the Companyâ€™s counsel. Â Permission to trade outside the window period (during any trading blackout period) will be granted only where the circumstances are extenuating and there appears to be no significant risk that the trade may subsequently be questioned.C. Exceptions to Window Period/Trading Blackout1.ESPP/Option Exercises. Â Officers and other employees who are eligible to do so may purchase stock under the Companyâ€™s Employee Stock Purchase Plan (â€œESPPâ€) on periodic designated dates in accordance with the ESPP without restriction to any particular period. Â Directors and officers and other members of management may exercise options for cash granted under the Companyâ€™s stock option plans without restriction to any particular period. Â However, the subsequent sale of the stock (including sales of stock in a cashless exercise) acquired upon the exercise of options or pursuant to the ESPP is subject to all provisions of this policy.2.Tax Withholding Transactions. This policy does not apply to the surrender of shares directly to the Company to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of restricted stock units, options or other equity awards granted under the Companyâ€™s equity compensation plans. Of course, any market sale of the stock received upon exercise or vesting of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.3.10b5-1 Automatic Trading Programs. Â In addition, purchases or sales of the Companyâ€™s securities made pursuant to, and in compliance with, a written plan established by a director, officer or other employee that meets the requirements of Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the â€œExchange Actâ€) (a â€œTrading Planâ€) may be made without restriction to any particular period provided that (i) the Trading Plan was established in good faith, in compliance with the requirements of Rule 10b5-1 of the Exchange Act, at the time when such individual was not in possession of inside information about the Company and the Company had not imposed any trading blackout period, (ii) the Trading Plan was reviewed and pre-approved by the Company prior to establishment to confirm compliance with this policy, any 10b5-1 trading plan or other applicable guidelines of the Company as may be in effect from time to time, and applicable securities laws and (iii) the Trading Plan allows for the cancellation of a transaction and/or suspension of the such Trading Plan upon notice and request by the Company to the individual if any proposed trade (a) fails to comply with applicable laws (e.g. exceeding the number of shares that may be sold under Rule 144) or (b) would create material adverse consequencesâ€‹.â€‹4.â€‹for the Company. Â The Company must be notified of the establishment of any such Trading Plan, any amendments to such Trading Plan and the termination of such Trading Plan.4.Domestic Relations Order. This policy does not apply to the acquisition or disposition of Outlookâ€™s securities pursuant to a domestic relations order, as defined in the Internal Revenue Code of 1986, as amended, or Title I of the Employee Retirement Income Security Act of 1974, as amended, or the rules thereunder.D. Pre-Clearance and Advance Notice of TransactionsIn addition to the requirements listed above, officers and directors and certain other employees and designated consultants of the Company who have been notified of their designation may not engage in any transaction in the Companyâ€™s securities, including any purchase or sale in the open market, loan, gift, pledge, hedge or other transfer of beneficial ownership without first obtaining pre-clearance of the transaction from the Companyâ€™s Chief Financial Officer (the â€œClearing Officerâ€) at least two business days in advance of the proposed transaction. This includes even proposed bona fide gifts involving the Companyâ€™s common stock or transfers for tax planning purposes in which the beneficial ownership and pecuniary interest in the transferred securities do not change. This requirement does not apply to transactions that are specifically exempted from this policy, including purchases or sales of the Companyâ€™s securities made pursuant to a Trading Plan that complies with this policy. Â The Clearing Officer will then determine whether the transaction may proceed and, if so, will direct the Compliance Coordinator (as identified in the Companyâ€™s Section 16 Compliance Program) to assist in complying with the reporting requirements under Section 16(a) of the Exchange Act, if any. Â Pre-cleared transactions not completed within three business days shall require new pre-clearance under the provisions of this paragraph. Â The Company may, at its discretion, shorten such period of time.Persons subject to pre-clearance must also give advance notice of an intent to exercise an outstanding stock option to the Clearing Officer. Â To the extent possible, advance notice of upcoming transactions to be effected pursuant to an established Trading Plan shall also be given to the Clearing Officer. Â Upon completion of any transaction, the officer or director or other member of management must immediately notify the Compliance Coordinator and any other individuals identified in Section 3 of the Companyâ€™s Section 16 Compliance Program so that the Company may assist in any Section 16 reporting obligations.E. Â Prohibition of Speculative or Short-term Trading. No officer, director, employee or consultant to the Company may engage in short sales, transactions in put or call options, hedging transactions, margin accounts, pledges, or other inherently speculative transactions with respect to the Companyâ€™s securities at any time.1. Hedging Transactions. Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit an employee, director or consultant of the Company to continue to own the Companyâ€™s securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the employee, director or consultant may no longer have the same objectives as the Companyâ€™s other shareholders. Therefore, employees, directors and consultants of the Company are prohibited from engaging in any such transactions.2. Margin Accounts and Pledged Securities. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customerâ€™s consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold inâ€‹.â€‹5.â€‹foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in the Companyâ€™s securities, employees, directors and consultants of the Company are prohibited from holding Company securities in a margin account or otherwise pledging the Companyâ€™s securities as collateral for a loan.3. Â Standing and Limit Orders. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when an employee, director or consultant of the Company is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on the Companyâ€™s securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the provisions herein.F. Short-Swing Trading/Control Stock/Section 16 ReportsOfficers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care not to violate the prohibition on short-swing trading (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (RuleÂ 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (FormsÂ 3, 4 and 5), which are enumerated and described in the Companyâ€™s Section 16 Compliance Program, and any notices

of sale required by Rule 144.IV. DURATION OF POLICYâ€™S APPLICABILITYThis policy continues to apply to your transactions in the Companyâ€™s securities or the securities of other public companies engaged in business transactions with the Company even after your employment, directorship or consultancy with the Company has terminated. Â If you are in possession of inside information when your relationship with the Company concludes, you may not trade in the Companyâ€™s securities or the securities of such other company until the information has been publicly disseminated or is no longer material. Further, if you leave the Company during a trading blackout period, then you may not trade in the Companyâ€™s securities or securities of other applicable companies until the trading blackout period has ended.V. PENALTIESAnyone who effects transactions in the Companyâ€™s securities or the securities of other public companies engaged in business transactions with the Company (or provides information to enable others to do so) on the basis of inside information is subject to both civil liability and criminal penalties, as well as disciplinary action by the Company. Â An employee, director or consultant who has questions about this policy should contact his or her own attorney or the Compliance Officer Â Please also see Frequently Asked Questions attached hereto as EXHIBIT A.â€‹6.â€‹EXHIBIT AFREQUENTLY ASKED QUESTIONS1.What is insider trading?A: Â Insider trading is the buying or selling of stocks, bonds, futures, or other securities by someone in who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in options (puts and calls) the price of which is linked to the underlying price of a companyâ€™s securities. It does not matter how many securities you buy or sell, or whether it has an effect on the price â€“ if you have or become aware of material nonpublic information and you trade, you have broken the law and violated our insider trading policy. In addition, our insider trading policy provides that if in the course of your relationship with the Company, you learn of confidential information that is material to another publicly trading company with which the Company does business, including a customer, supplier, partner or collaborator of the Company, you may not trade in that other companyâ€™s securities until the information becomes public or is no longer material to that other company.2.Why is insider trading illegal?A: Â If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the marketplace. Â Requiring those who have such information to disclose (the information to the public) or abstain (from trading) ensures an even playing field.3.What is material, nonpublic information?A: Â Information is material if it would influence a reasonable investor to buy or sell a stock, bond future or other security. Â This could mean many things â€“ financial, regulatory or clinical trial results, potential acquisitions or mergers, major contracts, etc. Information is nonpublic if it has not yet been released and disseminated to the public.4.Who can be guilty of insider trading?A: Â Anyone who engages in a transaction of securities while aware of or in possession of material, nonpublic information. Â It does not matter if you are not an executive officer or director, or even if you do not work at the Company â€“ if you know something material about the value of a security that not everyone else does, regardless of who you are, you can be found guilty of insider trading.5.Does the Company have an insider trading policy?A: Â Yes.6.What if I work in a foreign office?A: Â There is no difference. Â The policy and law applies to you. Because our securities trade on a U.S. securities exchange, the insider trading laws of the United States apply. Â The SEC (a U.S. government agency in charge of investor protection) and the Financial Industry Regulatory Authority (also known as â€œFINRAâ€) (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a companyâ€™s securities conducted by internationally-based individuals and firms. Inâ€‹7.â€‹addition, as an Outlook employee, contractor or consultant, our policies apply to you no matter where in the world you work.7.What if I donâ€™t buy or sell anything, but I tell someone else the information and they buy or sell? A: Â That is called â€œtipping.â€ You are the â€œtipperâ€ and the other person is called the â€œtippee.â€ Â If the tippee buys or sells based on that material nonpublic information, both you and the â€œtippeeâ€ might still be guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and the â€œtippeeâ€ might be guilty of insider trading too. As a result, you may not discuss material nonpublic information about the Company with anyone outside Outlook, including spouses, family members, friends, or business associates. This includes anonymous discussion on the Internet about the Company or companies with which the Company does business.8.What if I donâ€™t tell them the information itself, I just tell them whether they should buy or sell?A: Â That is still tipping, and you can still be found guilty of insider trading. Â According to our policies, you may never recommend to another person that they buy, hold or sell our securities or any derivative security related to our securities.9.What are the penalties if I trade on inside information, or tip off someone else?A: Â In addition to disciplinary action by the Company, which may include termination of employment, anyone found liable in a civil case for trading on inside information may need to pay the U.S. government an amount equal to any profit made or any loss avoided and may also face a penalty of up to three times this amount. Â Persons found liable for tipping inside information, even if they did not trade themselves, may face a penalty of up to three times the amount of any profit gained or loss avoided by everyone in the chain of tippees. In addition, anyone convicted of criminal insider trading can face prison terms and additional fines.10.What is â€œloss avoidedâ€?A: Â If you sell common stock or a related derivative security before the negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.11.Am I restricted from trading securities of any companies other than the Company (for example a customer or competitor of the Company)?A: Â Yes. U.S. insider trading laws restrict everyone from trading in a companyâ€™s securities based on material nonpublic information about that company, regardless of whether the person is directly connected with that company. Â Therefore, if you obtain material nonpublic information about another company, you should not trade in that companyâ€™s securities. Â You should be particularly conscious of this restriction if, through your position at the Company, you sometimes obtain sensitive, material information about other companies and their business dealings with the Company.â€‹8.â€‹12.So if I do not trade Outlook securities when I have material nonpublic information, and I donâ€™t â€œtipâ€ other people, I am in the clear, right?A: Â Not necessarily. Â Even if you do not violate U.S. law, you may still violate our policies. Â Our policies are stricter than the law requires so that we and our employees, contractors and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.13.So when can I buy or sell my Outlook securities?A: Â According to our policies, if you have material nonpublic information, you may not buy or sell our securities until the third trading day after that information is released or announced to the public. Â At that point, the information is considered public. Â Even if you do not have material, nonpublic information, you may not trade in our securities during any trading â€œblackoutâ€ period. Â And finally, directors, officers, and certain other employees and designated consultants of the Company who have been notified of their designation must pre-clear any purchases or sales of stock with the Clearing Officer two business days in advance of the proposed transaction.14.If I have an open order to buy or sell Outlook securities on the date a trading blackout is imposed, my broker will cancel the open order and wonâ€™t execute the trade, right?A: Â No. Â If you have any open orders at the time a trading blackout is imposed, it is your responsibility to cancel these orders with your broker. Â If you have an open order and it executes after the trading window closes, it is a violation of our insider trading policy and may also be a violation of the insider trading laws.15.Am I allowed to trade derivative securities of the Company? Or short the Companyâ€™s common stock?A: Â No. Â Under our policies, you may not trade in derivative securities related to our securities, which includes, but is not limited to publicly traded call and put options. Â In addition, under our policies, you may not engage in short selling of our securities at any time.â€œDerivative securitiesâ€ are securities other than common stock that are speculative in nature because they permit a person to leverage his or her investment using a relatively small amount of money. Examples of derivative securities include (but are not limited to) â€œput optionsâ€ and â€œcall options.â€ Â These are different from employee stock options, which are not derivative securities.â€œShort sellingâ€ is profiting when you expect the price of the stock to decline, and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is made through the expectation that the stock price will decrease during the period of borrowing.16.Why does the Company prohibit trading in derivative securities and short selling?A: Â Many companies with volatile stock prices have adopted such policies because of the temptation it represents to try to benefit from a relatively low cost method of trading on short-term swings in stock prices (without actually holding the underlying common stock) and encourages speculative trading. Â For this reason, we have decided to prohibit employees from such trading. Â As we are dedicated to building stockholder value, short selling our securities is adverse to our stated values and would not be received well by our stockholders.â€‹9.â€‹17.Can I purchase Outlook securities on margin or hold them in a margin account?A: Â Under our policies, you may not purchase our securities on margin or hold them in a margin account at any time.â€œPurchasing on marginâ€ is the use of borrowed money from a brokerage firm to purchase our securities. Â Holding our securities in a margin account includes holding the securities in an account in which the securities can be sold to pay a loan to the brokerage firm.18.Why does the Company prohibit me from purchasing Outlook securities on margin or holding them in a margin account?A: Â Margin loans are subject to a margin call whether or not you possess insider information at the time of the call. Â If your margin call were called at a time when you had insider information and you could not or did not supply other collateral, you and the Company could be subject to litigation based on your insider trading activities: the sale of the securities (through the margin call) when you possessed material nonpublic information. Â The sale would be attributed to you even though the lender made the ultimate determination to sell. Â The SEC takes the view that you made the determination to not supply the additional collateral and you are therefore responsible for the sale.19.Can I hedge my ownership position in the Company?A: Â Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds are prohibited by our insider trading policy. Since such hedging transactions allow you to continue to own the Companyâ€™s securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, you may no longer have the same objectives as the Companyâ€™s other shareholders. Therefore, our insider trading policy prohibits you from engaging in any such transactions.20.Can I exercise stock options during a trading blackout period or when I possess material nonpublic information?A: Â Yes. Â You may exercise the option and receive shares, but you may not sell the shares (even to pay the exercise price or any taxes due) or otherwise settle the option during a trading blackout period or any time that you have material nonpublic information. Â Also note that if you choose to exercise and hold the shares, you will be responsible at that time for any taxes due.21.Am I subject to the trading blackout period if I am no longer an employee of the Company?A: Â It depends. Â If your employment with the Company ends on a day when the window period is closed, you will be subject to the trading blackout period then in effect. Â If your employment with the Company ends on a day when the window period is open, you will not be subject to the next trading blackout. Â However, even if you are not subject to our trading blackout after you leave the Company, you should not trade in Outlook securities if you possess material nonpublic information. Â That restriction stays with you as long as the information you possess is material and not released by the Company.22.Can I gift securities while I possess material nonpublic information or during a trading blackout period?A: Â No. A gift of stock could subject you to insider trading liability if you are aware of material nonpublic information at the time of the gift and knew or were reckless in not knowing that the recipient would sell the securities prior to the disclosure of such information. Therefore, gifts may only be madeâ€‹10.â€‹when you are not in possession of material nonpublic information and not subject to a trading blackout period.23.What if I purchased publicly traded options or other derivative securities before I became an Outlook employee (or contractor or consultant)?A: Â The same rules apply as for employee stock options. Â You may exercise the publicly traded options at any time, but you may not sell such securities during a trading blackout period or at any time that you have material nonpublic information. Â When you become an Outlook employee, you must report to our Compliance Officer that you hold such publicly traded options or other derivative securities.24.May I own shares of a mutual fund that invests in the Company?A: Â Yes.25.Are mutual fund shares holding Outlook securities subject to the trading blackout periods?A: Â No. Â You may trade in mutual funds holding our securities at any time.26.May I use a â€œroutine trading programâ€ or â€œ10b5-1 planâ€?A: Â Yes, subject to the requirements discussed in our Insider Trading Policy, any 10b5-1 trading plan guidelines that may be in effect from time to time and applicable securities laws. Â A routine trading program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your stock broker through which you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, you must contact the Compliance Officer for approval.27.What happens if I violate our insider trading policy?A: Â Violation of our policies may result in severe personnel action, including a memo to your personnel file and up to and including termination of your employment or other relationship with the Company. Â In addition, you may be subject to criminal and civil enforcement actions by the government.28.Can I pledge my Company securities as collateral for a personal loan?A: No. Pledging your shares as collateral for a personal loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.29.Who should I contact if I have questions about our insider trading policy?A: Â You should contact the Compliance Officer.11.Exhibit 21.1Subsidiaries of the RegistrantdName of SubsidiaryState or Other JurisdictionOutlook Therapeutics Pty LtdAustraliaOutlook Therapeutics Limited (dormant subsidiary)England and WalesOutlook Therapeutics LimitedRepublic of Irelandâ€‹This list does not include joint ventures in which the Company has an ownership interest.Exhibit 23.1Consent of Independent Registered Public Accounting FirmWe consent to the incorporation by reference in the registration statements (Nos. 333-211362, 333-216081, 333-223064, 333-229685, 333-234024, 333-236471, 333-238318, 333-254777, 333-262731, 333-269770, 333-278343 and 333-281549) on Form S-8 and (Nos. 333-222387, 333-223063, 333-273979, 333-278209, 333-278340 and 333-278959) on Form S-3 of our report dated December 27, 2024, with respect to the consolidated financial statements of Outlook Therapeutics, Inc.â€‹/s/ KPMG LLPPhiladelphia, PennsylvaniaDecember 27, 2024Exhibit 31.1CERTIFICATIONSI, Lawrence A. Kenyon, certify that:1.I have reviewed this Annual Report on Form 10-K of Outlook Therapeutics, Inc. (the â€œregistrantâ€); and2.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.I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 registrantâ€™s disclosure controls and procedures and presented in this report my 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 registrantâ€™s internal control over financial reporting that occurred during the registrantâ€™s most recent fiscal quarter (the registrantâ€™s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrantâ€™s internal control over financial reporting; andâ€‹5.I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrantâ€™s auditors and the audit committee of the registrantâ€™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 registrantâ€™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 registrantâ€™s internal control over financial reporting.Date: December 27, 2024/s/ Lawrence A. KenyonLawrence A. KenyonChief Financial Officer and Interim Chief Executive Officer(Principal Executive, Financial and Accounting Officer)â€‹Exhibit 32.1CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TOSECTION 906 OF THE SARBANES-OXLEY ACT OF 2002I, Lawrence A. Kenyon, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, certify that the Annual Report of Outlook Therapeutics, Inc. (the â€œRegistrantâ€) on Form 10-K for the year ended September 30, 2024 (the â€œReportâ€) fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that information contained in the Report fairly presents in all material respects the financial condition and results of operations of the Registrant.Date: December 27, 2024By: /s/ Lawrence A. KenyonName: Lawrence A. KenyonTitle:Chief Financial Officer and Interim Chief Executive Officer(Principal Executive, Financial and Accounting Officer)â€‹A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.