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of ContentsUNITED STATESSECURITIES AND EXCHANGE COMMISSIONWashington, D.C. 20549_____FORM 10-Q_____xÂ Â Â Â QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934For the quarterly period ended September 30, 2024ORoÂ Â Â Â TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934For the transition period from _____to _____Commission File Number: 001-36296Carisma Therapeutics Inc.(Exact Name of Registrant as Specified in its Charter)_____Delaware26-2025616(State or other jurisdictionof incorporation or organization)(IRS EmployerIdentification No.)3675 Market Street, Suite 401Philadelphia, PA19104(Address of principal executive offices)(Zip Code)Registrantâ€™s telephone number, including area code: (267) 491-6422(Former Name or Former Address, if Changed Since Last Report)_____Securities registered pursuant to Section 12(b) of the Act:Title of each classTrading Symbol(s)Name of exchangeon which registeredCommon Stock, $0.001 par value per shareCARMThe Nasdaq Stock Market LLCIndicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No oIndicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Â§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No oIndicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmaller reporting company,â€ and â€œemerging growth companyâ€ in Rule 12b-2 of the Exchange Act.Large accelerated fileroAccelerated fileroNon-accelerated filerxSmaller reporting companyxEmerging growth companyoIf an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. oIndicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No xAs of NovemberÂ 5, 2024, the registrant had 41,750,109 shares of common stock, $0.001 par value per share, outstanding.Table of ContentsFORWARD-LOOKING STATEMENTSThis Quarterly Report on Form 10-Q contains express or implied forward-looking statements that are based on our managementâ€™s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or

financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q may include, but are not limited to, statements about:â€¢our ability to obtain additional financing;â€¢the timing and conduct of our pre-clinical studies and clinical trial of CT-0525 for solid tumors that overexpress human epidermal growth factor receptor 2, or HER2;â€¢the timing and conduct of our pre-clinical studies for fibrosis;â€¢our plans to conduct discovery and pre-clinical testing of the development of in vivo chimeric antigen receptor macrophage and monocyte, or CAR-M, therapeutics for up to twelve research targets, including Glypican-3, or GPC3, as well as two autoimmune and multiple other targets and indications in connection with our collaboration with ModernaTX, Inc., or Moderna;â€¢our ability to replicate in later clinical trials positive results found in pre-clinical studies and early-stage clinical trials of our product candidates;â€¢our ability to successfully enroll patients in our Phase 1 clinical trial of CT-0525 and complete clinical trials;â€¢our plans to conduct discovery and pre-clinical testing of other product candidates;â€¢our ability to enter into and realize the anticipated benefits of our research and development programs, strategic partnerships, research and licensing programs and academic and other collaborations;â€¢the timing of applying for and receiving, and our ability to maintain, marketing approvals from applicable regulatory authorities for our product candidates;â€¢our ability to obtain and maintain intellectual property protection and regulatory exclusivity for CT-0525 and any other product candidates we are developing or may develop in the future;â€¢acceptance of CT-0525 and any other product candidates we are developing or may develop, if and when approved, by patients, the medical community and third-party payors;â€¢our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash and cash equivalents;â€¢the potential advantages of our product candidates;â€¢our estimates regarding the potential market opportunity for our product candidates;â€¢our commercialization and manufacturing capabilities and strategy;â€¢the potential impact of public health epidemics or pandemics and of global economic developments on our business, operations, strategy and goals;â€¢our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;â€¢our competitive position;â€¢the impact of government laws and regulations;â€¢political and economic developments; andâ€¢such other matters as discussed in our Annual Report on Form 10-K for the year ended December 31, 2023 including Part I, Item 1A, â€œRisk Factorsâ€ and in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2024 and June 30, 2024 including Part II, Item 1A, "Risk Factors."In some cases, forward-looking statements can be identified by terminology such as â€œaim,â€ â€œanticipate,â€ â€œbelieve,â€ â€œestimate,â€ â€œexpect,â€ â€œintend,â€ â€œmay,â€ â€œmight,â€ â€œplan,â€ â€œpredict,â€ â€œproject,â€ â€œtarget,â€ â€œpotential,â€ â€œgoals,â€ â€œwill,â€ â€œwould,â€ â€œcould,â€ â€œshould,â€ â€œcontinueâ€ or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled â€œRisk Factorsâ€ and elsewhere in this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those expressed or implied by the forward-looking statements. No forward-looking statement is a promise or a guarantee of future performance.You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date iTable of Contentsof this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.In this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise requires, references to the â€œCompany,â€ â€œCarisma,â€ â€œwe,â€ â€œus,â€ and â€œourâ€ refer to Carisma Therapeutics Inc. (formerly Sesen Bio, Inc.) and its consolidated subsidiaries. References to â€œLegacy Carismaâ€ refer to CTx Operations, Inc. (formerly CARISMA Therapeutics Inc.) and references to â€œSesen Bioâ€ refer to Sesen Bio, Inc. prior to completion of the business combination on March 7, 2023 in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of September 20, 2022, as amended, by and among the Company, Legacy Carisma and Seahawk Merger Sub, Inc., a wholly owned subsidiary of the Company, or Merger Sub, pursuant to which Merger Sub merged with and into Legacy Carisma, with Legacy Carisma continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger, or the Merger.Pursuant to the Merger Agreement, we changed our name from â€œSesen Bio, Inc.â€ to â€œCarisma Therapeutics Inc.â€ Following the completion of the Merger, the business conducted by us became primarily the business conducted by Legacy Carisma, which is a biopharmaceutical company dedicated to developing a differentiated and proprietary cell therapy platform focused on engineered macrophages, cells that play a crucial role in both the innate and adaptive immune response.iiTable of ContentsCARISMA THERAPEUTICS INC.TABLE OF CONTENTSPagePART I.FINANCIAL INFORMATION1Item 1.Interim Financial Statements (Unaudited).1Consolidated Balance Sheets 1Consolidated Statements of Operations and Comprehensive Loss2Consolidated Statements of Convertible Preferred Stock and Stockholdersâ€™ Equity (Deficit)3Consolidated Statements of Cash Flows4Notes to the Interim Consolidated Financial Statements6Item 2.Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations.16Item 3.Quantitative and Qualitative Disclosures About Market Risk.29Item 4.Controls and Procedures.30PART II.OTHER INFORMATION31Item 1.Legal Proceedings.31Item 1A.Risk Factors.31Item 2.Unregistered Sales of Equity Securities and Use of Proceeds.89Item 5.Other Information.84Item 6.Exhibits.90SIGNATURES91iiiTable of ContentsPART Iâ€”FINANCIAL INFORMATIONItem 1. Financial Statements.CARISMA THERAPEUTICS INC.Unaudited Consolidated Balance Sheets(in thousands, except share and par value)September 30,2024December 31, 2023AssetsCurrent assets:Cash and cash equivalents$26,881Â $77,605Â Prepaid expenses and other assets7,256Â 2,866Â Total current assets34,137Â 80,471Â Property and equipment, net5,391Â 6,764Â Right of use assets â€“ operating leases2,322Â 2,173Â Deferred financing costs208Â 146Â Total assets$42,058Â $89,554Â Liabilities and Stockholders' (Deficit) Equity Current liabilities:Accounts payable$1,728Â $3,933Â Accrued expenses4,542Â 7,662Â Deferred revenue682Â 1,413Â Operating lease liabilities1,386Â 1,391Â Finance lease liabilities1,074Â 544Â Other current liabilities1,146Â 965Â Total current liabilities10,558Â 15,908Â Deferred revenue41,250Â 45,000Â Operating lease liabilities761Â 860Â Finance lease liabilities96Â 328Â Other long-term liabilities519Â 926Â Total liabilities53,184Â 63,022Â Commitments and contingencies (Note 6)Stockholdersâ€™ (deficit) equity:Preferred stock $0.001 par value, 5,000,000 shares authorized, none issued or outstandingâ€”Â â€”Â Common stock $0.001 par value, 350,000,000 shares authorized, 41,750,109 and 40,609,915 shares issued and outstanding at SeptemberÂ 30, 2024 and DecemberÂ 31, 2023, respectively41Â 40Â Additional paid-in capital276,777Â 271,594Â Accumulated deficit(287,944)(245,102)Total stockholdersâ€™ (deficit) equity(11,126)26,532Â Total liabilities and stockholdersâ€™ (deficit) equity $42,058Â $89,554Â See accompanying notes to unaudited interim consolidated financial statements.1Table of ContentsCARISMA THERAPEUTICS INC.Unaudited Consolidated Statements of Operations and Comprehensive Loss(in thousands, except share and per share data)Three Months EndedSeptember 30,Nine Months EndedSeptember 30,20242023202420232Collaboration revenues$3,385Â $3,827Â $15,979Â $10,630Â Operating expenses:Research and development11,326Â 19,551Â 44,095Â 54,710Â General and administrative5,203Â 6,620Â 16,208Â 22,201Â Total operating expenses16,529Â 26,171Â 60,303Â 76,911Â Operating loss(13,144)(22,344)(44,324)(66,281)Change in fair value of derivative liabilityâ€”Â â€”Â â€”Â (84)Interest income, net442Â 941Â 1,482Â 641Â Pre-tax loss(12,702)(21,403)(42,842)(65,724)Income tax expenseâ€”Â â€”Â â€”Â (197)Net loss$(12,702)$(21,403)$(42,842)$(65,921)Share information:Net loss per share of common stock, basic and diluted(0.31)(0.53)(1.04)(2.11)Weighted-average shares of common stock outstanding, basic and diluted41,588,03540,285,85841,357,52831,209,904Comprehensive lossNet loss$(12,702)$(21,403)$(42,842)$(65,921)Unrealized gain on marketable securitiesâ€”Â 108Â â€”Â 414Â Comprehensive loss$(12,702)$(21,295)$(42,842)$(65,507)See accompanying notes to unaudited interim consolidated financial statements.2Table of ContentsCARISMA THERAPEUTICS INC.Unaudited Consolidated Statements of Convertible Preferred Stock and Stockholdersâ€™ Equity (Deficit)(in thousands, except share data)Convertible preferred stockStockholdersâ€™ Equity (Deficit)Common stockAdditionalpaid-in capitalAccumulatedothercomprehensiveÂ (loss) incomeAccumulateddeficitNoncontrollinginterestsTotalSharesAmountSharesAmountBalance at December 31, 2023â€”Â $â€”Â 40,609,915$40Â $271,594Â $â€”Â $(245,102)$â€”Â $26,532Â Exercise of stock optionsâ€”Â â€”Â 1,579â€”Â 2Â â€”Â â€”Â â€”Â 2Â Stock-based compensationâ€”â€”Â â€”Â â€”Â 1,057Â â€”Â â€”Â â€”Â 1,057Â Sale of common stock under Open Market Sales Agreement, net of issuance costsâ€”â€”Â 931,2501Â 2,281Â â€”Â â€”Â â€”Â 2,282Â Net lossâ€”â€”Â â€”â€”Â â€”Â â€”Â (18,978)â€”Â (18,978)Balance at March 31, 2024â€”â€”Â 41,542,74441Â 274,934Â â€”Â (264,080)â€”Â 10,895Â Exercise of stock optionsâ€”â€”2,231â€”2Â â€”â€”2Stock-based compensationâ€”â€”Â â€”â€”625â€”â€”â€”Â 625Â Net lossâ€”â€”Â â€”â€”â€”â€”(11,162)â€”Â (11,162)Balance at June 30, 2024â€”â€”Â 41,544,97541Â 275,561Â â€”Â (275,242)â€”Â 360Â Stock-based compensationâ€”Â â€”Â â€”Â â€”Â 1,115Â â€”Â â€”Â â€”Â 1,115Sale of common stock under Open Market Sales Agreement, net of issuance costsâ€”Â â€”Â 205,134Â â€”Â 101Â â€”Â â€”Â â€”Â 101Net lossâ€”Â â€”Â â€”Â â€”Â â€”Â â€”Â (12,702)â€”Â (12,702)Balance at September 30, 2024â€”$â€”Â 41,750,109$41Â $276,777Â $â€”Â $(287,944)$â€”Â $(11,126)Balance at December 31, 20228,700,885$107,808Â 2,217,737$2Â $1,197Â (41)(158,223)$14,395Â $(142,670)Stock-based compensationâ€”â€”Â â€”â€”Â 265Â â€”Â â€”Â â€”Â 265Â Unrealized gain on marketable securitiesâ€”â€”Â â€”â€”Â â€”Â 177Â â€”Â â€”Â 177Â Issuance of common stock for cash in pre-closing financingâ€”â€”Â 3,730,6084Â 30,636Â â€”Â â€”Â â€”Â 30,640Â Issuance of common stock upon settlement of convertible promissory note, accrued interest, and related derivative liabilityâ€”â€”Â 5,059,3385Â 42,442Â â€”Â â€”Â â€”Â 42,447Â Issuance of common stock to Sesen Bio shareholders in reverse capitalizationâ€”â€”Â 10,374,27210Â 72,034Â â€”Â â€”Â â€”Â 72,044Â Conversion of convertible preferred stock and non-controlling interests to common stock(8,700,885)(107,808)18,872,71119Â 122,185Â â€”Â â€”Â (14,395)107,809Â Net lossâ€”â€”Â â€”Â â€”Â â€”Â (24,642)â€”Â (24,642)Balance at March 31, 2023â€”â€”Â 40,254,66640Â 268,759Â 136Â (182,865)â€”Â 86,070Â Exercise of stock optionsâ€”â€”14,910Â â€”52Â â€”â€”52Stock-based compensationâ€”â€”Â â€”Â â€”Â 330Â â€”Â â€”Â â€”Â 330Â Unrealized gain on marketable securitiesâ€”â€”Â â€”Â â€”Â â€”Â 129Â â€”Â â€”Â 129Â Net lossâ€”â€”Â â€”Â â€”Â â€”Â (19,876)â€”Â (19,876)Balance at June 30, 2023â€”â€”Â 40,269,57640Â 269,141Â 265Â (202,741)â€”Â 66,705Â Exercise of stock optionsâ€”Â â€”Â 34,860Â â€”Â 40Â â€”Â â€”Â â€”Â 40Â Stock-based compensationâ€”Â â€”Â â€”Â â€”Â 848Â â€”Â â€”Â â€”Â 848Â Unrealized gain on marketable securitiesâ€”Â â€”Â â€”Â â€”Â â€”Â â€”Â 108Â â€”Â â€”Â 108Â Net lossâ€”Â â€”Â â€”Â â€”Â â€”Â (21,403)â€”Â (21,403)Balance at September 30, 2023â€”$â€”Â 40,304,436$40Â 270,029$373Â $(224,144)$â€”Â $46,298Â See accompanying notes to unaudited interim consolidated financial statements.3Table of ContentsCARISMA THERAPEUTICS INC.Unaudited Consolidated Statement of Cash Flows (in thousands)Nine Months EndedSeptember 30,20242023Cash flows from operating activities:Net loss$(42,842)$(65,921)Adjustment to reconcile net loss to net cash used in operating activities:Depreciation and amortization expense2,685Â 2,115Â Stock-based compensation expense2,797Â 1,443Â Reduction in the operating right of use assets5,570Â 4,066Â Amortization of debt discountâ€”Â 1,283Â Change in fair value of derivative liabilityâ€”Â 84Â Accretion on marketable securitiesâ€”Â (741)Write-off of property and equipment74Â â€”Â Non-cash interest expense192Â 117Â Gain on sale of sale-leaseback (82)â€”Â Changes in operating assets and liabilities:Prepaid expenses and other assets(4,460)484Â Accounts payable(2,228)372Â Accrued expenses(3,120)(3,534)Deferred revenue(4,481)(1,274)Operating lease liabilities(5,823)(3,574)Other liabilities153Â â€”Â Net cash used in operating activities(51,565)(65,080)Cash flows from investing activities:Purchase of marketable

securitiesâ€”Â (34,460)Proceeds from the sale of marketable securitiesâ€”Â 97,000Â Purchases of property and equipment(123)(571)Net cash (used in) provided by investing activities(123)61,969Â Cash flows from financing activities:Cash, cash equivalents and restricted cash acquired in connection with the reverse recapitalizationâ€”Â 37,903Â Payment of reverse recapitalization finance costsâ€”Â (5,814)Proceeds from the issuance of common stock in pre-closing financingâ€”Â 30,640Â Payment of principal related to finance lease liabilities(1,158)(1,151)Proceeds from failed sale-leaseback arrangement686Â 1,183Â Payment of finance liability from failed sale-leaseback arrangement(983)(628)Payment of deferred financing costsâ€”Â (146)Proceeds from the exercise of stock options4Â 92Â Sale of common stock under Open Market Sales Agreement, net of issuance costs2,415Â â€”Â Net cash provided by financing activities964Â 62,079Â Net (decrease) increase in cash, cash equivalents and restricted cash(50,724)58,968Â Cash, cash equivalents and restricted cash at beginning of the period77,605Â 24,194Â Cash, cash equivalents and restricted cash at end of the period$26,881Â $83,162Â See accompanying notes to unaudited interim consolidated financial statements.4Table of ContentsCARISMA THERAPEUTICS INC.Unaudited Consolidated Statement of Cash Flows (in thousands)Nine Months EndedSeptember 30,20242023Supplemental disclosures of cash flow information:Cash paid for interest$153Â $283Â Supplemental disclosure of non-cash financing and investing activities:Conversion of convertible preferred stock and non-controlling interests upon Merger$â€”Â $122,204Â Conversion of convertible promissory note, accrued interest and derivative liability upon Merger$â€”Â $42,447Â Unrealized gain on marketable securities$â€”Â $414Â Financing costs in accounts payable$23Â $â€”Â Reclassification of deferred financing costs to additional paid-in capital$9Â $â€”Â Right of use assets obtained in exchange for new operating lease liabilities$5,719Â $908Â Disposal of property and equipment in exchange for reduction in finance lease liability$396Â $â€”Â Right of use assets obtained in exchange for new financing lease liabilities$1,660Â $â€”Â Property and equipment in accounts payable$â€”Â $295Â See accompanying notes to unaudited interim consolidated financial statements.5Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial Statements(1)Â Â Â Â BackgroundCarisma Therapeutics Inc., a Delaware corporation (collectively with its subsidiaries, the Company), is a clinical-stage cell therapy company focused on using the Companyâ€™s proprietary cell therapy platform to develop transformative immunotherapies to treat cancer and other serious diseases. The Company has created this comprehensive cell therapy platform to enable the therapeutic use of engineered macrophages and monocytes, which belong to a subgroup of white blood cells called myeloid cells. The Companyâ€™s focus is its proprietary chimeric antigen receptor macrophage and monocyte (CAR-M) cell therapy platform, which redirects macrophages against specific tumor associated antigens and enables targeted anti-tumor immunity by utilizing genetically modified myeloid cells (macrophages and monocytes) to express chimeric antigen receptors (CARs), enabling these potent innate immune cells to recognize specific tumor associated antigens on the surface of tumor cells. The Company has an ex vivo oncology program and an in vivo program. In addition, the Company utilizes its cell therapy platform to engineer macrophages with the potential to treat fibrosis.Ex Vivo Oncology Program â€” The Company's lead product candidate, CT-0525, is intended to treat solid tumors that overexpress human epidermal growth factor receptor 2 (HER2), a protein found on the surface of a variety of solid tumors, including breast cancer, gastric cancer, esophageal cancer, salivary gland cancer, and others. CT-0525 utilizes a novel approach to CAR-M therapy that engineers patientsâ€™ monocytes directly, without ex vivo differentiation into macrophages. The Company believes that engineering monocytes directly (CAR-Monocyte) will result in a therapy with favorable attributes compared to engineering after ex vivo differentiation (CAR-Macrophage) and that this approach has the potential to improve upon the anti-tumor effect seen with CAR-Macrophages. In Vivo Program (Moderna Collaboration) â€” In addition to the Company's clinical program in ex vivo cell therapy, the Company has an in vivo mRNA/lipid nanoparticle (LNP) CAR-M program in partnership with ModernaTX Inc. (Moderna). This collaboration utilizes Moderna's mRNA/LNP technology, together with the Company's CAR-M platform technology, to create novel in vivo off the shelf gene therapy products.Fibrosis Program â€” Using its macrophage and monocyte engineering platform, the Company is also pursuing early research and development of multiple assets for the potential treatment of diseases beyond oncology, including fibrosis and other immunologic and inflammatory diseases. In the second quarter of 2024, the Company achieved pre-clinical proof of concept in its liver fibrosis program, demonstrating the anti-fibrotic potential of engineered macrophages in two liver fibrosis models. The Company's first product candidate to enter clinical development, CT-0508, was the first CAR-Macrophage to be evaluated in a human clinical trial and was an anti-HER2 product candidate. The Company also enrolled six patients in a sub-study evaluating the co-administration of CT-0508 and pembrolizumab, a programmed cell death protein 1 checkpoint inhibitor, evaluating the safety and tolerability of the co-administration, along with several customary secondary endpoints.In late March 2024, the Company and its board of directors approved a revised operating plan to reduce monthly operating expenses and conserve cash, which it began implementing in April 2024. Pursuant to the revised operating plan, the Company has prioritized CT-0525 as the Company's lead product candidate going forward, ceased further development of CT-0508, paused further development of CT-1119 pending additional financing, reduced its workforce, including employees engaged in research and development and general and administration activities, and decreased spending on other non-essential activities. As of July 2024, all clinical activities related to the Phase 1 clinical trial of CT-0508 and its sub-study utilizing CT-0508 in combination with pembrolizumab have been completed and no further development of CT-0508 is planned. The Company completed its workforce reduction and paid the majority of related costs in the second quarter of 2024. (2)Â Â Â Â Development-Stage Risks and LiquidityThe Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of $287.9 million as of SeptemberÂ 30, 2024. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales from its product candidates currently in development. 6Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial StatementsManagement expects its cash and cash equivalents of $26.9 million as of SeptemberÂ 30, 2024 are sufficient to sustain planned operations into the third quarter of 2025. As a result, the Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The Company's cash forecast contains estimates and assumptions, and management cannot predict the timing of all cash receipts and expenditures with certainty. Variances from management's estimates and assumptions could impact the Company's liquidity prior to the third quarter of 2025. The accompanying unaudited interim 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 unaudited interim consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liability that might result from the outcome of this uncertainty.Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to, private placements of equity and/or debt, other offerings of equity and/or debt securities, licensing arrangements and/or marketing arrangements. There is no assurance that such financing will be available when needed. The Company also intends to continue to reassess its expense allocation.The Company is subject to those risks associated with any specialty biotechnology company that has substantial expenditures for research and development. There can be no assurance that the Companyâ€™s research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants.(3)Â Â Â Â Summary of Significant Accounting PoliciesInterim Financial StatementsThe summary of significant accounting policies is included in the Companyâ€™s audited consolidated financial statements and related notes as of and for the year ended DecemberÂ 31, 2023 found in the Annual Report filed on Form 10-K filed with the Securities and Exchange Commission (SEC) on April 1, 2024.The accompanying unaudited interim consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). Any references in these notes to applicable guidance are meant to refer to GAAP as found in Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) promulgated by the Financial Accounting Standards Board (FASB). The accompanying unaudited interim consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the unaudited interim consolidated financial statements) considered necessary to present fairly the Companyâ€™s financial position as of SeptemberÂ 30, 2024 and its results of operations for the three and nine months ended SeptemberÂ 30, 2024 and 2023. Operating results for the three and nine months ended SeptemberÂ 30, 2024 are not necessarily indicative of the results that may be expected for the year ending DecemberÂ 31, 2024. The unaudited interim consolidated financial statements, presented herein, do not contain all of the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes as of and for the year ended DecemberÂ 31, 2023 found in the Annual Report filed on Form 10-K filed with the SEC on April 1, 2024.Use of EstimatesThe preparation of unaudited interim 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 unaudited interim consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates. Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are determined to be necessary.7Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial StatementsSignificant areas that require managementâ€™s estimates include accrued research and development expenses.Fair Value of Financial InstrumentsManagement believes that the carrying amounts of the Companyâ€™s financial instruments, including cash equivalents and accounts payable, approximate fair value due to the short-term nature of those instruments. Fair Value MeasurementsThe Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:â€¢Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.â€¢Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.â€¢Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.The following fair value hierarchy table presents information about the Companyâ€™s assets and liabilities measured at fair value on a recurring basis:(in thousands)Fair value measurement at reporting date using(Level 1)(Level 2)Â (Level 3)September 30, 2024Assets:Cash equivalents â€“ money markets accounts$21,676Â $â€”Â $â€”Â December 31, 2023Â Â Â Assets:Â Â Â Cash equivalents â€“ money markets accounts$62,999Â $â€”Â $â€”Â During the nine months ended September 30, 2024 and 2023, there were no transfers between Level 1, Level 2 and Level 3.Concentration of credit riskFinancial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash and cash equivalents.Segment informationOperating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.8Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial StatementsNet loss per shareBasic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for

basic net loss per share due to the fact that when a net loss exists, potentially dilutive securities are not included in the calculation as their impact is anti-dilutive.The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:September 30,20242023Stock options8,777,6386,515,345Recently issued accounting pronouncementsIn December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (ASU 2023-09), which expands the disclosures required for income taxes. This ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The amendment should be applied on a prospective basis while retrospective application is permitted. The Company is currently evaluating the effect of this pronouncement on its disclosures.(4)Â Â Â Â Prepaid Expenses and other assetsPrepaid expenses and other assets consisted of the following (in thousands):September 30, 2024December 31, 2023Research and development$1,434Â $278Â Novartis credit (Note
6)4,000Â â€”Â Deposits1,248Â 891Â Insurance504Â 402Â Other70Â 1,295Â $7,256Â $2,866Â (5)Â Â Â Â Accrued ExpensesAccrued expenses consisted of the following (in thousands):September 30, 2024December 31, 2023Research and development$1,059Â $3,131Â Professional fees1,138Â 1,366Â Compensation and related expenses2,305Â 3,100Â Other40Â 65Â $4,542Â $7,662Â 9Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial Statements(6)Â Â Â Â Commitments and ContingenciesLeasesThe Company has operating leases for its laboratory and office space in Philadelphia, Pennsylvania. The Companyâ€™s operating leases have term end dates ranging from 2024 to 2029. The Company also has obligations under an arrangement for the use of certain laboratory equipment that are classified as finance leases that commenced in 2022 and have end dates ranging from 2024 to 2026. Effective February 2024, the Company renewed an existing operating lease with an end date through 2026. In April 2024, in connection with the revised operating plan, the Company notified the lessor that it would terminate the lease effective August 2024. In July 2024, the Company entered into an amendment extending the termination of the lease to June 2025 with an option to extend to December 2025. In September 2024, the Company modified existing finance leases and failed sale-leaseback arrangements by assigning the rights and obligations of certain underlying assets to an unrelated third party. The modifications resulted in a reduction of its finance lease right of use (ROU) assets and related lease liability of $0.4Â million. In addition, the Company recorded a reduction of its failed sale-leaseback liability and gain on the sale of the corresponding assets of $0.1Â million. The Companyâ€™s operating and finance lease ROU assets and the related lease liabilities are initially measured at the present value of future lease payments over the lease term. The Company is responsible for payment of certain real estate taxes, insurance and other expenses on certain of its leases. These amounts are generally considered to be variable and are not included in the measurement of the ROU assets and lease liability. The Company accounts for non-lease components, such as maintenance, separately from lease components.The Company carries laboratory equipment from failed sale-leasebacks, as property and equipment, net on the accompanying unaudited interim consolidated balance sheets. The ongoing lease payments are recorded as reductions to the finance liability and interest expense. As of SeptemberÂ 30, 2024, the Company had a $1.7 million financing liability recorded in other current liabilities and other long-term liabilities on the unaudited interim consolidated balance sheets.The elements of the lease costs were as follows (in thousands):Nine Months Ended September 30,20242023Operating lease cost$4,226Â $4,322Â Finance lease cost:Amortization of lease assets1,321Â 890Â Interest on lease liabilities192Â 117Â Total finance lease cost1,513Â 1,007Â Variable lease cost768Â 1,216Â Short term lease cost503Â â€”Â Total lease cost$7,010Â $6,545Â 10Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial StatementsLease term and discount rate information related to leases was as follows:September 30,20242023Weighted-average remaining lease term (in years)Operating leases2.43.6Finance leases1.11.8Weighted-average discount rateOperating leases9.7Â %10.0Â %Finance leases9.0Â %9.0Â %Supplemental cash flow information was as follows (in thousands):Nine Months EndedSeptember 30,20242023Cash paid for amounts included in the measurement of lease liabilities:Operating cash used in operating leases$4,478Â $4,028Â Operating cash used in finance leases$192Â $117Â Financing cash used in finance leases$1,158Â $1,151Â Future maturities of lease liabilities were as follows as of SeptemberÂ 30, 2024 (in thousands):Operating LeasesFinance LeasesFiscal year ending:2024 (remaining three months)$1,329Â $271Â 2025219Â 942Â 2026226Â 20Â 2027233Â â€”Â 2028240Â â€”Â Thereafter184Â â€”Â Total future minimum payments2,431Â 1,233Â Less imputed interest(284)(63)Present value of lease liabilities$2,147Â $1,170Â Manufacturing and Supply AgreementIn March 2023, the Company entered into a manufacturing and supply agreement (Novartis Agreement) with Novartis Pharmaceuticals Corporation (Novartis) for the manufacturing of the Companyâ€™s CT-0508 product candidate. The Novartis Agreement is for five years and shall renew automatically for additional one-year periods unless and until terminated by either party. In addition to paying to manufacture the product, the Company will also pay $1.0 million per calendar year, payable in quarterly payments, for reserved capacity starting on the date on which the Novartis site is declared ready to produce CT-0508 as determined by the Company. In the event of termination without cause by the Company, a termination fee equal to $4.0 million will be payable by Carisma to Novartis which, pursuant to the terms of the agreement, can be credited in full against amounts due for a substitute product. On June 26, 2024, in furtherance of its revised operating plan, the Company terminated the Novartis Agreement. Upon termination, the Company incurred a termination fee equal to $4.0Â million, which was paid in the third quarter of 2024. A 11Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial Statementsprepaid asset was recorded as the Company has separately agreed with Novartis that if Novartis and the Company enter into an agreement for the tech transfer of another product to Novartis on or before December 31, 2024, then the $4.0Â million termination fee shall be credited in full or in part against any amounts due from the Company to Novartis under such agreement relating to the substitute product. If an agreement is not entered into or the current agreement is not modified by December 31, 2024, the $4.0Â million prepaid asset will be written-off to operating expenses. ContingenciesLiabilities for loss contingencies, arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment and/or remediation can be reasonably estimated. No such loss contingencies were probable nor reasonably estimable as of SeptemberÂ 30, 2024.(7)Â Â Â Â Stockholdersâ€™ EquityOpen Market Sales AgreementOn May 12, 2023, the Company entered into an Amended and Restated Open Market Sale AgreementSM with Jefferies LLC, as sales agent, pursuant to which the Company may offer and sell shares of its common stock with an aggregate offering price of up to $100.0Â million under an â€œat-the-market" offering program. During the nine months ended September 30, 2024, the Company sold 1,136,384 shares and received net proceeds of $2.4Â million in connection with the Company's "at-the-market" offering program.(8)Â Â Â Â Stock-based Compensation2017 Stock Incentive PlanThe Company adopted the CARISMA Therapeutics Inc. 2017 Stock Incentive Plan, as amended (the Legacy Carisma Plan), that provided for the grant of incentive stock options to employees, directors, and consultants. The maximum term of options granted under the Legacy Carisma Plan was ten years, and stock options typically vested over a four-year period. The Companyâ€™s stock options vest based on the terms in the awards agreements and generally vest over four years. Upon completion of the Merger, the Company assumed the Legacy Carisma Plan and the outstanding and unexercised options issued thereunder and ceased granting awards under the Legacy Carisma Plan.2014 Stock Incentive PlanStock options outstanding under the 2014 Amended and Restated Stock Incentive Plan (the 2014 Plan) generally vest over a four-year period and are exercisable for a period of ten years from the date of grant. As of SeptemberÂ 30, 2024, approximately 3.8 million shares of common stock remained available for issuance.2014 Employee Stock Purchase PlanThe Carisma Therapeutics Inc. 2014 Employee Stock Purchase Plan had 0.2 million shares of common stock available for issuance as of SeptemberÂ 30, 2024.12Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial StatementsThe following table summarizes stock option activity for the nine months ended September 30, 2024:OptionsWeightedaverageexerciseprice Weightedaverageremainingcontractualterm (years)Aggregate Intrinsic Value (in thousands)Outstanding as of December 31,
20236,023,370$3.94Â Exercised(3,810)0.99Â $4Â Granted3,766,7651.76Â Forfeited (1,008,687)4.70Â Outstanding as of September 30,
20248,777,638$2.92Â 7.9$620Â Exercisable as of September 30, 20243,871,741$2.37Â 6.4$619Â The weighted-average grant-date per share fair values of options granted during the nine months ended September 30, 2024 and 2023 were $1.44 and $4.42, respectively. The fair values in the nine months ended September 30, 2024 and 2023 were estimated using the Black-Scholes option-pricing model based on the following assumptions:Nine Months Ended September 30,20242023Risk-free interest rate3.77% - 4.59%2.92% - 4.03%Expected term6 years6 yearsExpected volatility103.00% - 112.10%57.77% - 65.00%Expected dividend yieldâ€”Â â€”Â Stock-Based Compensation ExpenseThe Company recorded stock-based compensation expense in the following expense categories in its accompanying unaudited interim consolidated statements of operations:Three Months Ended September 30,Nine Months Ended September 30,2024202320242023Research and development$384Â $418Â $776Â $452Â General and
administrative731Â 430Â 2,021Â 991Â $1,115Â $848Â $2,797Â $1,443Â In connection with the revised operating plan, 869,800 options were forfeited during the nine months ended September 30, 2024, resulting in a reduction in stock-based compensation expense related to research and development and general and administrative employees. The Company recognized stock-based compensation expense of $0.2 million related to the modification of Sesen Bio options assumed in connection with the Merger during nine months ended September 30, 2023. Compensation cost for awards not vested as of SeptemberÂ 30, 2024 was $10.8 million and will be expensed over a weighted-average period of 2.7 years.(9)Â Â Â Â Related-Party TransactionsThe Company has outstanding licensing and scientific research agreements with the University of Pennsylvania (Penn), a significant stockholder as of September 30, 2023. As of December 31, 2023, Penn was no longer a significant stockholder. The Company recognized $0.3Â million and $0.6Â million of research and development expenses for the three and nine months ended September 30, 2023 related to the Penn License Agreement. 13Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial StatementsThe Company has a collaboration and license agreement with Moderna, a significant stockholder (Note 10). (10)Â Â Â Â Moderna Collaboration and License AgreementIn January 2022, the Company entered into the Moderna License Agreement, which provides for a broad strategic collaboration to discover, develop and commercialize in vivo engineered CAR-M therapeutics in oncology. Moderna has the right to designate up to twelve research targets as development targets under this collaboration. While the collaboration was initially limited to oncology, in September 2024, the companies agreed to expand the collaboration to discover, develop and commercialize in vivo engineered CAR-M therapeutics in specific autoimmune diseases. As a result, Moderna nominated two autoimmune research targets. As of September 30, 2024, the first seven of the twelve research targets, including the autoimmune targets, have been nominated and all programs are currently in the discovery or pre-clinical phase.Upon Modernaâ€™s designation of a development target (and payment of a related development target designation milestone) for commencement of pre-clinical development of a product candidate, the Company will grant Moderna an exclusive worldwide, sublicensable royalty bearing license to develop, manufacture and commercialize the product candidate.Under the terms of the Moderna License Agreement, Moderna made an upfront non-refundable payment of $45.0 million to the Company. Assuming Moderna develops and commercializes 12 products, each directed to a different development target, the Company is eligible to receive up to between $247.0 million and $253.0 million per product in development target designation, development, regulatory and commercial milestone payments. Moderna also will reimburse the Company for all costs incurred by the Company in connection with its research and development activities under the Moderna License Agreement plus a reasonable margin for the respective services performed (with a minimum commitment to reimburse $10.0 million in research and development costs over the first three years from execution of the Moderna License Agreement). The Company is also eligible to receive tiered mid-to-high single digit royalties of net sales of any products that are commercialized under the agreement, which may be, subject to reductions. In addition, Moderna has agreed to cover the cost the Company incurs for certain milestone payments and royalties that the Company owes as a licensor under one of its intellectual property in-license agreements with Penn, which is sublicensed to Moderna under the Moderna License Agreement. Moderna may deduct these royalties in part from any royalties owed to the Company. The Moderna License Agreement terminates on a product-by-product basis upon the latest of expiration of the applicable product patents, expiration of regulatory exclusivity and the tenth anniversary of first commercial sale, unless terminated earlier by the Company or Moderna.At commencement, the Company identified several potential performance obligations within the Moderna License Agreement, including research and development services on research targets, option rights held by Moderna,

a non-exclusive royalty-free license to use the Companyâ€™s intellectual property to conduct research and development activities and participation on the joint steering committee (JSC). The Company determined that there were 2 performance obligations comprised of (i) research and development services and (ii) option rights.For the research and development services, the stand-alone selling price was determined considering the expected passthrough costs and cost of the research and development services and a reasonable margin for the respective services. The material rights from the option rights were valued based on the estimated discount at which the option is priced and the Companyâ€™s estimated probability of the optionsâ€™ exercise as of the time of the agreement. The transaction price allocated to research and development services is recognized as collaboration revenues as the research and development services are provided to satisfy the underlying obligation related to the research and development target. The transfer of control occurs over this period and, in managementâ€™s judgment, is the best measure of progress towards satisfying the performance obligation.The transaction price of $45.0Â million allocated to the options rights, which are considered material rights, will be recognized in the period that Moderna exercises or determines not to exercise its option right to license and commercialize the designated development target. In June 2024, the Company received notice from Moderna that Moderna had designated the first development candidate, an in vivo CAR-macrophage targeting GPC3 that is designed to treat solid tumors, including hepatocellular carcinoma. Pursuant to the terms of the Moderna License Agreement, the designation triggered a $2.0Â million milestone payment from 14Table of ContentsCARISMA THERAPEUTICS INC.Notes to the Interim Consolidated Financial StatementsModerna to the Company. As a result, the Company recognized collaboration revenue of $2.0Â million. On July 3, 2024, the Company received the $2.0Â million payment from Moderna. In addition, the Company reduced its $45.0Â million deferred revenue liability associated with the option rights by recognizing $3.8Â million in collaboration revenue, which represents a proportional reduction based on the 12 potential early-stage research targets. The Company included the $45.0 million up-front and nonrefundable payment and $73.9 million of variable consideration for expected research and development services to be performed during the five-year contract term, inclusive of passthrough costs, in the transaction price as of the outset of the arrangement. During the three months ended September 30, 2024 and 2023, the Company recognized $3.4 million and $3.8 million, respectively, of collaboration revenues. During the nine months ended September 30, 2024 and 2023, the Company recognized $16.0 million and $10.6 million, respectively, of collaboration revenues. Collaboration revenues for the nine months ended September 30, 2024 include $3.8Â million of deferred option rights revenue recognition and $2.0Â million of milestones.The Company recognized $35.0Â million and $3.8Â million, respectively, of research and development services and option right collaboration revenues since inception of the Moderna License Agreement through SeptemberÂ 30, 2024. The following table includes estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied as of SeptemberÂ 30, 2024 (in thousands):Transaction price unsatisfiedPerformance obligations:Research and development$38,954Â Option rights41,250Â Total performance obligations$80,204Â Amounts due to the Company for satisfying the revenue recognition criteria or that are contractually due based upon the terms of the collaboration agreements are recorded as accounts receivable in the Companyâ€™s unaudited interim consolidated balance sheets. Contract liabilities consist of amounts received prior to satisfying the revenue recognition criteria, which are recorded as deferred revenue in the Companyâ€™s unaudited interim consolidated balance sheets.The following table summarizes the changes in deferred revenue (in thousands):Nine Months Ended September 30,20242023Balance at the beginning of the period $46,413Â $47,459Â Deferral of revenue9,498Â 9,356Â Recognition of unearned revenue(13,979)(10,630)Balance at the end of the period$41,932Â $46,185Â The current portion of deferred revenue represents advanced payments received from Moderna for costs expected to be incurred by the Company within the next twelve months. The noncurrent portion of deferred revenue represents the unearned portion of the upfront, non-refundable and non-creditable payment allocated to Moderna's option rights of $41.3 million, which is not expected to be recognized within the next 12 months.(11)Â Â Â Â Subsequent EventsThe Company has evaluated subsequent events from the balance sheet date through NovemberÂ 7, 2024, the issuance date of these unaudited interim consolidated financial statements, and has not identified any additional items that have not previously been mentioned elsewhere requiring disclosure. 15Table of ContentsItem 2. Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations.The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited interim consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section titled â€œRisk Factorsâ€ in our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2024 and June 30, 2024 and in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated by these forward-looking statements.OverviewWe are a clinical-stage cell therapy company focused on using our proprietary cell therapy platform to develop transformative immunotherapies to treat cancer and other serious diseases. We have created this comprehensive cell therapy platform to enable the therapeutic use of engineered macrophages and monocytes, which belong to a subgroup of white blood cells called myeloid cells. Our focus is our proprietary chimeric antigen receptor macrophage and monocyte, or CAR-M, cell therapy platform, which redirects macrophages against specific tumor associated antigens and enables targeted anti-tumor immunity by utilizing genetically modified myeloid cells (macrophages and monocytes) to express chimeric antigen receptors, or CARs, enabling these potent innate immune cells to recognize specific tumor associated antigens on the surface of tumor cells. We have an ex vivo oncology program and an in vivo program. In addition, we utilize our cell therapy platform to engineer macrophages with the potential to treat fibrosis.â€¢Ex Vivo Oncology Program â€” Our lead product candidate, CT-0525, is intended to treat solid tumors that overexpress human epidermal growth factor receptor 2, or HER2, a protein found on the surface of a variety of solid tumors, including breast cancer, gastric cancer, esophageal cancer, salivary gland cancer, and others. CT-0525 utilizes a novel approach to CAR-M therapy that engineers patientsâ€™ monocytes directly, without ex vivo differentiation into macrophages. We believe that engineering monocytes directly (CAR-Monocyte) will result in a therapy with favorable attributes compared to engineering after ex vivo differentiation (CAR-Macrophage) and that this approach has the potential to improve upon the anti-tumor effect seen with CAR-Macrophages. In November 2023, we received United States Food and Drug Administration, or FDA, clearance of our investigational new drug application, or IND, for CT-0525, we treated the first patient in May 2024. CT-0525 also received FDA Fast Track designation in the second quarter of 2024. We expect to report initial data from the CT-0525 Phase 1 clinical trial in the first quarter of 2025.â€¢In Vivo Program (Moderna Collaboration) â€” In addition to our clinical program in ex vivo cell therapy, we have an in vivo mRNA/lipid nanoparticle, or LNP, CAR-M program in partnership with ModernaTX Inc., or Moderna. This collaboration utilizes Moderna's mRNA/LNP technology, together with our CAR-M platform technology, to create novel in vivo off the shelf gene therapy products. In November 2023, we announced pre-clinical proof of concept with this approach. In December 2023 we announced the lead candidate nomination for the first target in the partnership. In June 2024, we announced the designation of the first development candidate, or Development Candidate, under the collaboration. This Development Candidate targets GPC3, and is designed to treat solid tumors, including hepatocellular carcinoma, or HCC, the most prevalent type of liver cancer and the fastest-rising cause of cancer-related death in the U.S. While the collaboration was initially focused on oncology programs, in September 2024, we announced an expansion of the collaboration to develop two in vivo CAR-M therapies for autoimmune disease. As of September 30, 2024, seven of the twelve research targets, including the two autoimmune targets, have been nominated by Moderna with five remaining to be nominated.â€¢Fibrosis Program â€” Using our macrophage and monocyte engineering platform, we are also pursuing early research and development of multiple assets for the potential treatment of diseases beyond oncology, including fibrosis and other immunologic and inflammatory diseases. We are developing engineered macrophages to enhance the innate activity of macrophages with the potential to resolve liver fibrosis. In the second quarter of 2024, the Company achieved pre-clinical proof of concept in its liver fibrosis program, demonstrating the anti-fibrotic potential of engineered macrophages in two liver fibrosis models. We expect to nominate a development candidate in this program in the first quarter of 2025.16In late March 2024, the Company and its board of directors approved a revised operating plan to reduce monthly operating expenses and conserve cash, which it began implementing in April 2024. Pursuant to the revised operating plan, the Company has prioritized CT-0525 as the Company's lead product candidate going forward, ceased further development of CT-0508, will continue our fully funded program on in vivo CAR-M therapy in oncology and autoimmune disease in collaboration with Moderna, paused further development of CT-1119 pending additional financing, reduced its workforce, including employees engaged in research and development and general and administration activities, and decreased spending on other non-essential activities. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to, private placements of equity and/or debt, other offerings of equity and/or debt securities, licensing arrangements and/or marketing arrangements. We will also continue to reassess our expense allocation.Our PipelineUsing our proprietary macrophage and monocyte cell therapy platform, we are developing a pipeline of product candidates, with an initial focus on advancing ex vivo autologous and in vivo CAR-M therapies for the treatment of solid tumors. We are also pursuing early research and development of multiple assets for the potential treatment of diseases beyond oncology, including fibrosis and other immunologic and inflammatory diseases. All of our programs, other than the targets/programs under the collaboration with Moderna, are wholly owned.Our lead product candidate, CT-0525, a CAR-Monocyte intended to treat solid tumors that overexpress HER2, utilizes a novel approach to CAR-M therapy that engineers patients' monocytes directly, without ex vivo differentiation into macrophages, as we did for CT-0508. The CAR-Monocyte approach utilizes a single day manufacturing process, which enables the manufacture of up to ten billion cells from a single apheresis and leverages an automated manufacturing process. In addition, the CAR-Monocyte approach has the potential to improve upon the potential anti-tumor effect of a CAR-Macrophage. By increasing the cell yield, a CAR-Monocyte enables a larger dose than a CAR-Macrophage. In addition, CAR-Monocyte has the potential for improved persistence and trafficking, which were observed in pre-clinical studies. We believe that the increased cell yield, and the improved persistence and trafficking may improve tumor control. Moreover, based on the final results relating to our Phase 1 clinical trial of CT-0508, which are preliminary and limited, we believe that repeat dosing of CT-0525 in patients with HER2 overexpressing cancers could prolong pharmacologic efficacy and response. Our Phase 1 clinical trial for CT-0525 is open for enrollment and we treated the first patient in May 2024. The FDA granted CT-0525 Fast Track designation in June 2024 and we expect to report initial data from the clinical trial in the first quarter of 2025. In September 2024, we submitted a protocol amendment for our Phase 1 study to allow for the expansion of the study to include additional alternative dosing regimens. Data from the study will dictate the utilization of specific alternative dosing regimens.Our first product candidate to enter clinical development, CT-0508, was the first CAR-Macrophage to be evaluated in a human clinical trial and was an anti-HER2 product candidate. While the clinical trial has shown the product to be well tolerated, feasible to manufacture, to initiate remodeling of the tumor microenvironment and to have an anti-tumor effect, as of July 2024, all clinical activities related to the Phase 1 clinical trial of CT-0508 and its sub-study utilizing CT-0508 in combination with pembrolizumab have been completed and no further development of CT-0508 is planned. We recently completed analysis of circulating tumor DNA, or ctDNA, from 13 patients enrolled in groups 1 and 2 of our Phase 1 clinical trial of CT-0508. Based on preliminary results assessed to date, we observed that 75% (n=6/8) of evaluable HER2 3+ patients experienced a ctDNA reduction, indicating direct tumor killing activity. Zero percent (n=0/5) of evaluable HER2 2+ patients experienced a ctDNA reduction. In the 6 patients that experienced a ctDNA reduction, the median decrease was 81% (range 33%-93% decrease in ctDNA 4-weeks post treatment with CT-0508). We also enrolled six patients in a sub-study evaluating the co-administration of CT-0508 and pembrolizumab, a programmed cell death protein 1 checkpoint inhibitor, evaluating the safety and tolerability of the co-administration, along with several customary secondary endpoints. The study met its primary endpoints of safety, tolerability and manufacturing feasibility of CT-0508. The data demonstrate that the combination therapy was generally well-tolerated with no dose-limiting toxicities. The best overall response was stable disease (n=1/6), with corticosteroid administration and / or loss of human leukocyte antigen, or HLA, expression being key limitations to potential efficacy in three of the patients who experienced progressive disease. The correlative data concerning immune activation suggest a synergistic potential for the combination of CAR-M with pembrolizumab based on increased peripheral blood T cell clonality, T cell activation, and frequency of effector memory cluster of differentiation, or CD,8 T cells compared to CT-0508

alone. Supported by these 17safety and translational findings, as well as other results from the clinical trial of CT-0508, we intend to explore the strategy of combining CAR-M with pembrolizumab or another checkpoint inhibitor in the CT-0525 program.Our pipeline also includes CT-1119, a mesothelin-targeted CAR-Monocyte, that has been paused pursuant to our revised operating plan pending additional financing.In addition to the development of ex vivo CAR-M cell therapies, we are developing in vivo CAR-M cell therapies, wherein immune cells are directly engineered within the patientâ€™s body. To advance our in vivo CAR-M therapeutics, in January 2022, we established the collaboration with Moderna by entering into the Moderna License Agreement to develop up to twelve in vivo CAR-M therapies. As part of the Moderna License Agreement, we received a $45.0 million up-front cash payment and an investment by Moderna in the form of a $35.0 million convertible promissory note, which converted into shares of common stock in connection with the consummation of the Merger, in addition to future research funding and the opportunity for milestone payments and royalties. This collaboration utilizes Moderna's mRNA/LNP technology, together with our CAR-M platform technology, to create novel in vivo off the shelf gene therapy products. While the collaboration was initially limited to oncology, in September 2024, the companies agreed to expand the collaboration to discover, develop and commercialize in vivo engineered CAR-M therapeutics in specific autoimmune diseases. As of September 30, 2024, the first seven of the twelve research targets, including the autoimmune research targets, have been nominated and all programs are currently in the discovery or pre-clinical phase. Since entering the agreement, we have made significant progress advancing this program. In the fourth quarter of 2023, we presented pre-clinical data from this collaboration demonstrating that CAR-M can be directly produced in vivo, successfully redirecting endogenous myeloid cells against tumor-associated antigens using mRNA/LNP. Additionally, the pre-clinical data demonstrated feasibility, tolerability, and early efficacy of in vivo CAR-M against metastatic solid tumors. In December 2023, we announced the nomination of the collaborationâ€™s first lead candidate and in June 2024, we received notice from Moderna that Moderna intended to advance the first lead candidate into development by designating it as the first Development Candidate under the collaboration. The first Development Candidate is an in vivo CAR-M targeting Glypican-3, or GPC3 that is designed to treat HCC. We believe that GPC3 is a validated target in HCC, an area of significant unmet medical need. Pursuant to the terms of the Moderna License Agreement, the designation triggered a $2.0 million milestone payment from Moderna to us. On July 3, 2024, we received the $2.0 million payment from Moderna. In November 2024, we announced new pre-clinical data on our anti-GPC3 in vivo CAR-M therapy for treating HCC. These pre-clinical data demonstrate robust anti-tumor activity.In addition to acting as a first line of defense in the innate immune system, macrophages and monocytes are found in all tissues in the body where they serve key regulatory functions such as wound healing, termination of immune responses and tissue regeneration. Using our macrophage and monocyte engineering platform, we are pursuing early research and development of multiple assets for the potential treatment of diseases beyond oncology, including fibrosis and other immunologic and inflammatory diseases. In the second quarter of 2024, we achieved pre-clinical proof of concept in our liver fibrosis program, demonstrating the anti-fibrotic potential of engineered macrophages in two liver fibrosis models. We expect to nominate a development candidate in our fibrosis program in the first quarter of 2025.To date, we have not yet commercialized any products or generated any revenue from product sales and have financed our operations primarily with proceeds from sales of our preferred stock, proceeds from our collaboration with Moderna, research tax credits, convertible debt financing, closing of pre-closing financing, and completion of the Merger. Our operations to date have been limited to organizing and staffing the Company, business planning, capital raising, establishing and maintaining our intellectual property portfolio, building our pipeline of product candidates, conducting drug discovery activities, undertaking pre-clinical studies, manufacturing process development studies, conducting early-stage clinical trials, and providing general and administrative support for these operations. We have devoted substantially all of our financial resources and efforts to pursuing discovery, research and development of our product candidates. Financial OperationsOur net losses were $42.8 million and $65.9 million for the nine months ended September 30, 2024 and 2023, respectively. As of SeptemberÂ 30, 2024, we had $26.9 million in cash and cash equivalents and an accumulated deficit of $287.9 million. We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct our clinical trial of CT-0525 and continue our other product development efforts. If we obtain marketing approval for CT-0525 or any other product candidate we are developing or develop in the future, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. We believe our revised operating plan approved in March 2024 by our board of directors will facilitate cost control to support further development of our product candidates and other research and development programs. 18As of September 30, 2024, we had 41,750,109 shares of common stock issued and outstanding. We will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise additional capital or obtain adequate funds on acceptable terms, we may be required to further delay, limit, reduce or terminate our discovery and product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. However, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract from our discovery and product development efforts. Considering the anticipated benefits of our revised operating plan, we believe that we have cash and cash equivalents sufficient to sustain our operating expenses and capital expenditure requirements into the third quarter of 2025.Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand business, maintain discovery and product development efforts, diversify our pipeline of product candidates or even continue operations.Revised Operating PlanIn late March 2024, our board of directors approved a revised operating plan to reduce our monthly operating expenses and conserve cash, which we began implementing in April 2024. Pursuant to the revised operating plan, the Company has prioritized CT-0525 as the Company's lead product candidate going forward, ceased further development of CT-0508, paused further development of CT-1119 pending additional financing, will continue our fully funded program on in vivo CAR-M therapy in oncology and autoimmune disease in collaboration with Moderna, continue research efforts in our fibrosis program, reduced our workforce by 39 full-time employees (representing approximately 37% of our total workforce), including employees engaged in research and development and general and administration activities, and decreased spending on other non-essential activities. We completed our workforce reduction and paid the majority of related costs in the second quarter of 2024. As of September 30, 2024, $0.3 million in severance costs from our workforce reduction remains and will be paid in equal installments through April 2025. As of July 2024, all clinical activities related to the clinical trial of CT-0508 and its sub-study utilizing CT-0508 in combination with pembrolizumab have been completed.These changes have resulted in certain operating efficiencies which support our cash runway and support our product development programs as well as any potential collaborations or other strategic relationships we may enter into. We have incurred $1.6 million which consists primarily of one-time employee termination benefits directly associated with the workforce reduction, a majority of which has been paid as of September 30, 2024.As part of the revised operating plan, on June 26, 2024, we notified Novartis Pharmaceuticals Corporation, or Novartis, of our termination of the Manufacturing and Supply Agreement, dated March 1, 2023, relating to the manufacture of our first product candidate to enter clinical development, CT-0508, or the Manufacturing Agreement. The termination is effective July 31, 2024. As a result of the termination of the Manufacturing Agreement, we incurred a termination fee of $4.0 million, or the Termination Fee, which we paid in the third quarter of 2024. We have separately agreed with Novartis that if we enter into an agreement for the tech transfer of another product, or a Substitute Product, to Novartis on or before December 31, 2024, then the Termination Fee shall be credited in full or in part against any amounts due to Novartis under such agreement relating to the Substitute Product.Financial Operations OverviewCollaboration RevenuesTo date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for the foreseeable future. Our revenues to date have been generated from the Moderna License Agreement. Moderna reimburses us for all costs incurred by it in connection with its research and development activities under the Moderna License Agreement plus a reasonable margin for the respective services performed. We expect that our revenue for at least the next several years will be derived primarily from the Moderna License Agreement, other current 19collaboration agreements and any additional collaborations that we may enter into in the future. To date, we have not received any royalties under the Moderna License Agreement.Research and Development ExpensesResearch and development expenses consist primarily of costs incurred for our research activities, including discovery efforts and the development of product candidates, and include:â€¢expenses incurred to conduct the necessary pre-clinical studies and clinical trials required to obtain regulatory approval;â€¢salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;â€¢costs of funding research performed by third parties, including pursuant to agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our pre-clinical studies and clinical trials;â€¢expenses incurred under agreements with contract manufacturing organizations, or CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing pre-clinical study and clinical trial materials;â€¢costs of outside consultants, including their fees, stock-based compensation and related travel expenses;â€¢the costs of laboratory supplies and acquiring materials for pre-clinical studies;â€¢facility-related expenses, which include direct depreciation costs of equipment and expenses for rent and maintenance of facilities and other operating costs; andâ€¢third-party licensing fees.Research and development activities are central to our business model. Product candidates in later stages of clinical development will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to decrease in the remainder of 2024 as we have begun to implement our revised operating plan, including a reduction in workforce, prioritization of CT-0525 and a pause in development of CT-1119. We expect that our expenses will increase again in future years as we continue to advance our clinical trials and potentially progress additional product candidates.The successful development of our current or future 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 development of any product candidates. The success of CT-0525 and our other product candidates will depend on several factors, including the following:â€¢successfully completing pre-clinical studies;â€¢successfully initiating future clinical trials;â€¢successfully enrolling patients in and completing clinical trials;â€¢scaling up manufacturing processes and capabilities to support clinical trials of CT-0525 and any other product candidate;â€¢applying for and receiving marketing approvals from applicable regulatory authorities;â€¢obtaining and maintaining intellectual property protection and regulatory exclusivity for CT-0525 and any other product candidates the Company is developing or may develop in the future;â€¢making arrangements with third-party manufacturers, or establishing commercial manufacturing capabilities, for both clinical and commercial supplies of our product candidates;â€¢establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;â€¢acceptance of CT-0525 and any other product candidates, if and when approved, by patients, the medical community and third-party payors;â€¢effectively competing with other therapies;â€¢obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;â€¢maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;â€¢not infringing, misappropriating or otherwise violating othersâ€™ intellectual property or proprietary rights; andâ€¢maintaining a continued acceptable safety profile of our products following receipt of any marketing approvals.20A change in the outcome of any of these variables with respect to the development, manufacture or commercialization activities 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 we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we could be required to expend significant

additional financial resources and time on the completion of clinical development. Product commercialization will take several years, and we expect to spend a significant amount in development costs.General and Administrative ExpensesGeneral and administrative expenses consist primarily of personnel expenses, including salaries, benefits and stock-based compensation expense for employees in executive, finance, accounting, business development and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation and maintenance, and costs not otherwise included in research and development expenses, legal fees related to intellectual property and corporate matters as well as fees for accounting and consulting services.We expect that our general and administrative expenses will decrease in 2024, as we have begun to implement our revised operating plan, including reducing our workforce and decreasing expenses related to non-essential activities. In addition, our 2023 expenses included a significant amount of non-recurring costs related to the Merger that are described below. We expect that our expenses will increase again in future years as we continue to incur costs associated with being a public company.Interest Income, NetInterest income consists of interest earned on our excess cash. Interest expense consisted of interest on our finance leases and our convertible promissory note that was entered into concurrently with the Moderna License Agreement including non-cash interest expense associated with the amortization of the debt discount. The convertible promissory note was converted into common stock upon the closing of the Merger.Change in Fair Value of Derivative LiabilityChange in fair value of the derivative liability for the redemption feature of our convertible promissory note reflected the non-cash charge for changes in the fair value of the derivative liability that was subject to re-measurement at each balance sheet date through the settlement of the convertible promissory note upon the closing of the Merger at which time the redemption feature was derecognized.Income TaxesSince inception, we have incurred significant net losses. We have provided a valuation allowance against the full amount of our deferred tax assets since, in our opinion, based upon our historical and anticipated future losses, it is more likely than not that the benefits will not be realized. As of SeptemberÂ 30, 2024, we remained in a full valuation allowance position. The utilization of our net operating loss carryforwards, or NOLs, may be subject to a substantial annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue of 1986, or the Code, respectively, as well as similar state provisions. We have recorded a valuation allowance on all of our deferred tax assets, including deferred tax assets related to NOLs. 21Results of OperationsComparison of the Three Months Ended September 30, 2024 and 2023 (in thousands)Three Months EndedSeptember 30,20242023Collaboration revenues$3,385Â $3,827Â Operating expenses:Research and development11,326Â 19,551Â General and administrative5,203Â 6,620Â Total operating expenses16,529Â 26,171Â Operating loss(13,144)(22,344)Change in fair value of derivative liabilityâ€”Â â€”Â Interest income, net442Â 941Â Pre-tax loss(12,702)(21,403)Income tax expenseâ€”Â â€”Â Net loss$(12,702)$(21,403)Collaboration RevenuesCollaboration revenues were $3.4 million and $3.8 million for the three months ended September 30, 2024 and 2023, respectively. The decrease was primarily related to the research and development activities completed under the Moderna License Agreement. Research and Development ExpensesWe track outsourced development, outsourced personnel costs and other external research and development costs of our CT-0508, CT-0525, and CT-1119 programs. We do not track internal research and development costs on a program-by-program basis. The following table summarizes our research and development expenses for the three months ended September 30, 2024 and 2023 (in thousands):Three Months EndedSeptember 30,20242023CT-0508 (1)$702Â $3,094Â CT-05252,033Â 2,894Â CT-1119 (1)183Â 285Â Personnel costs, including stock-based compensation (2)4,315Â 5,226Â Other clinical and pre-clinical development expenses592Â 1,423Â Facilities and other expenses3,501Â 6,629Â Total research and development expenses$11,326Â $19,551Â (1) Consistent with our revised operating plan, development activities with respect to CT-0508 ceased, and as of July 2024, all remaining clinical activities related to CT-0508 were completed. We have also elected to pause further development of CT-1119, a mesothelin-targeted CAR-Monocyte, pending additional financing.(2) In late March 2024, we approved a revised operating plan to reduce monthly operating expenses and conserve cash, which we began implementing in April 2024, including a reduction of workforce of which a majority of associated costs were paid in the second quarter of 2024. Research and development expenses for the three months ended September 30, 2024 were $11.3 million, compared to $19.6 million for the three months ended September 30, 2023. The decrease of $8.3 million was primarily due to 22implementation of our revised operating plan in the second quarter of 2024 in which we halted further development of CT-0508, paused development of CT-1119 and implemented a workforce reduction. As result of the revised operating plan, we experienced a decrease of $2.4 million related to halting development of CT-0508 and a $0.1 million decrease from pausing the development of CT-1119. In addition, the implementation of the revised operating plan resulted in a decrease in facilities and other expenses of $3.1 million due to less laboratory supplies and laboratory space needs and a $0.9 million decrease in direct personnel costs due to a reduction in headcount. Further, we experienced a $0.9 million decrease in direct costs associated with pre-clinical development of CT-0525 due to the timing of the development program and a decrease of $0.9 million in other clinical and pre-clinical development expenses resulting from the timing of certain studies in our in vivo collaboration with Moderna.General and Administrative ExpensesThe following table summarizes our general and administrative expenses for the three months ended September 30, 2024 and 2023 (in thousands):Three Months EndedSeptember 30,20242023Personnel costs, including stock-based compensation (1)$2,229Â $1,751Â Professional fees2,247Â 3,546Â Facilities and supplies269Â 580Â Insurance, taxes, and fees353Â 574Â Other expenses105Â 169Â Total general and administrative expenses$5,203Â $6,620Â (1) In late March 2024, we approved a revised operating plan to reduce monthly operating expenses and conserve cash, which we began implementing in April 2024, including a reduction of workforce of which a majority of associated costs were paid in the second quarter of 2024. General and administrative expenses for the three months ended September 30, 2024 were $5.2 million, compared to $6.6 million for the three months ended September 30, 2023. The decrease of $1.4Â million was primarily due to our revised operating plan in which we recognized a $1.3Â million decrease in professional fees as a result of our patent portfolio and expanding infrastructure in 2023, a $0.3 million decrease in facilities and supplies due to a decrease in office expenditures, a $0.2Â million decrease in insurance costs, and a $0.1 million decrease in other expenses related to a decline in travel costs, partially offset by a $0.5 million increase in personnel costs driven by an increase in stock-based compensation.Interest Income, NetWe recognized $0.4Â million and $0.9Â million in interest income, net for the three months ended September 30, 2024 and 2023, respectively, primarily attributable to interest earned on excess cash, partially offset by interest on our finance leases. 23Comparison of the Nine Months Ended September 30, 2024 and 2023 (in thousands)Nine Months EndedSeptember 30,20242023Collaboration revenues$15,979Â $10,630Â Operating expenses:Research and development44,095Â 54,710Â General and administrative16,208Â 22,201Â Total operating expenses60,303Â 76,911Â Operating loss(44,324)(66,281)Change in fair value of derivative liabilityâ€”Â (84)Interest income, net1,482Â 641Â Pre-tax loss(42,842)(65,724)Income tax expenseâ€”Â (197)Net loss$(42,842)$(65,921)Collaboration RevenuesCollaboration revenues were $16.0 million and $10.6 million for the nine months ended September 30, 2024 and 2023, respectively. The increase was primarily related to Moderna's Development Candidate nomination which resulted in $5.8 million of collaboration revenue consisting of $3.8 million of deferred option rights revenue recognition and $2.0 million of milestone revenue that was recognized in the second quarter of 2024.Research and Development ExpensesWe track outsourced development, outsourced personnel costs and other external research and development costs of our CT-0508, CT-0525, and CT-1119 programs. We do not track internal research and development costs on a program-by-program basis. The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and 2023 (in thousands):Nine Months EndedSeptember 30,20242023CT-0508 (1)$4,397Â $8,680Â CT-05257,217Â 6,108Â CT-1119 (1)420Â 763Â Personnel costs, including stock-based compensation (2)15,621Â 15,241Â Other clinical and pre-clinical development expenses3,327Â 4,403Â Facilities and other expenses13,113Â 19,515Â Total research and development expenses$44,095Â $54,710Â (1) Consistent with our revised operating plan, development activities with respect to CT-0508 ceased, and as of July 2024, all remaining clinical activities related to CT-0508 were completed. We have also elected to pause further development of CT-1119, a mesothelin-targeted CAR-Monocyte, pending additional financing.(2) In late March 2024, we approved a revised operating plan to reduce monthly operating expenses and conserve cash, which we began implementing in April 2024, including a reduction of workforce of which a majority of associated costs were paid in the second quarter of 2024. 24Research and development expenses for the nine months ended September 30, 2024 were $44.1 million, compared to $54.7 million for the nine months ended September 30, 2023. The decrease of $10.6 million was primarily due to implementation of our revised operating plan in the second quarter of 2024 in which we halted further development of CT-0508, paused development of CT-1119 and implemented a workforce reduction. As result of the revised operating plan, we experienced a decrease of $4.3 million related to halting development of CT-0508 and $0.3 million from pausing the development of CT-1119. In addition, the implementation of the revised operating plan resulted in a decrease in facilities and other expenses by $6.4 million due to less laboratory supplies and laboratory space needs and a decrease of $1.1 million in other clinical and pre-clinical development expenses resulting from the timing of certain studies in our in vivo collaboration with Moderna, partially offset by a $1.1 million increase in direct costs associated with pre-clinical development of CT-0525 due to the timing of the development program, and a $0.4 million increase in direct personnel costs which includes severance payments associated with the revised operating plan.General and Administrative ExpensesThe following table summarizes our general and administrative expenses for the nine months ended September 30, 2024 and 2023 (in thousands):Nine Months EndedSeptember 30,20242023Personnel costs, including stock-based compensation (1)$6,895Â $9,549Â Professional fees6,487Â 9,657Â Facilities and supplies1,342Â 847Â Insurance, taxes, and fees955Â 1,530Â Other expenses529Â 618Â Total general and administrative expenses$16,208Â $22,201Â (1) In late March 2024, we approved a revised operating plan to reduce monthly operating expenses and conserve cash, which we began implementing in April 2024, including a reduction of workforce of which a majority of associated costs were paid in the second quarter of 2024. General and administrative expenses for the nine months ended September 30, 2024 were $16.2 million, compared to $22.2 million for the nine months ended September 30, 2023. The decrease of $6.0 million was primarily due to our revised operating plan in which we recognized a $3.2 million decrease in professional fees as a result of non-recurring legal costs associated with the Merger, a $2.7 million decrease in personnel costs including severance and related costs resulting from the Merger in 2023 offset by an increase in salaries and headcount, stock-based compensation and severance costs associated with the revised operating plan, a $0.6 million decrease in taxes and insurance, partially offset by a $0.5 million increase in facilities and supplies due to a rise in office expenditures.Interest Income, NetWe recognized $1.5 million in interest income, net for the nine months ended September 30, 2024, which was primarily attributable to interest earned on excess cash, partially offset by interest on our finance leases. We recognized $0.6 million in interest income, net for the nine months ended September 30, 2023, which was attributable primarily to the accelerated amortization of the debt discount as a result of the settlement of the convertible promissory note at the closing of the Merger and interest expense on the outstanding principal balance associated with the convertible promissory note issued to Moderna through March 7, 2023, offset by interest income of $2.7 million.Change in Fair Value of Derivative LiabilityWe recognized a $0.1 million non-cash charge for the nine months ended September 30, 2023, for the increase in fair value of the derivative liability associated with the redemption feature of the convertible promissory note with Moderna, which 25was attributable to the timing in which we expected the accrued settlement event to occur. There was no change in fair value of derivative liability for the nine months ended September 30, 2024.Income Tax ExpenseWe recorded $0.2 million of income tax expense for the nine months ended September 30, 2023 based on projected taxable income for the year ended DecemberÂ 31, 2023. We had no such income tax expense for the nine months ended September 30, 2024.Liquidity and Capital ResourcesSources of LiquidityAs of September 30, 2024, we had $26.9 million in cash and cash equivalents and an accumulated deficit of $287.9 million. To date, we have not yet commercialized any products or generated any revenue from product sales and have financed operations primarily with proceeds from sales of preferred stock, proceeds from our collaboration with Moderna, research tax credits and convertible debt financing. Under the Moderna License Agreement we anticipate receiving $73.9 million over the term of the contract for expected research and development services to be performed by us, inclusive of pass-through costs, to be billed quarterly. Through September 30, 2024, we have generated $40.7 million of collaboration revenues related to research and development services, option rights, and milestone payments. Under the terms of the Moderna License Agreement, assuming Moderna

develops and commercializes 12 products, each directed to a different development target, we are eligible to receive up to between $247.0 million and $253.0 million per product in development target designation, development, regulatory and commercial milestone payments. On April 17, 2023, we filed a universal shelf registration statement on Form S-3, which was declared effective on May 2, 2023, or the Registration Statement. Under the Registration Statement, we may offer and sell up to $300.0 million of a variety of securities, including debt securities, common stock, preferred stock, depositary shares, subscription rights, warrants and units from time to time in one or more offerings at prices and on terms to be determined at the time of the offering. On May 12, 2023, we entered into an Amended and Restated Open Market Sale AgreementSM, or the Sale Agreement, with Jefferies LLC, as sales agent, pursuant to which we may offer and sell shares of our common stock with an aggregate offering price of up to $100.0 million under an â€œat-the-market" offering program. As of September 30, 2024, we have sold 1,362,917 shares for gross proceeds of $3.2 million.Cash FlowsThe following table shows a summary of our cash flows for the nine months ended September 30, 2024 and 2023 (in thousands):Nine Months EndedSeptember 30,20242023Cash (used in) provided byOperating activities$(51,565)$(65,080)Investing activities(123)61,969Â Financing activities964Â 62,079Â Net change in cash, cash equivalents and restricted cash$(50,724)$58,968Â Cash Flows from Operating ActivitiesDuring the nine months ended September 30, 2024, we used $51.6 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $42.8 million that was offset by $11.2 million of non-cash charges primarily related to depreciation and amortization expense, stock-based compensation, reductions in the operating right of use, or ROU assets, and a $20.0 million net change in our operating assets and liabilities attributable to the timing in which we pay our vendors for research and development activities.During the nine months ended September 30, 2023, we used $65.1 million of net cash in operating activities. Cash used in operating activities reflected our net loss of $65.9 million that was offset by $8.4 million of non-cash charges primarily 26related to depreciation and amortization expense, stock-based compensation, reductions in the operating ROU assets, and accretion on marketable securities, and a $7.5 million net change in our operating assets and liabilities attributable to the timing in which we pay our vendors for research and development activities.Cash Flows from Investing ActivitiesDuring the nine months ended September 30, 2024, cash used in investing activities reflected purchases of property and equipment.During the nine months ended September 30, 2023, we received $62.0 million of net cash from investing activities. Cash provided by investing activities reflected $97.0 million of proceeds from the sale of marketable securities, partially offset by purchases of marketable securities of $34.5 million and the purchase of property and equipment of $0.6 million.Cash Flows from Financing ActivitiesDuring the nine months ended September 30, 2024, we received $1.0 million of net cash from financing activities, primarily attributable to $2.4Â million from the sale of common stock in connection with the Sale Agreement, net of issuance costs, and $0.7 million in proceeds from failed-sale leaseback arrangements, partially offset by $1.2 million in payments of principal related to finance lease liabilities, and $0.9 million in payments of finance liability from failed-sale leaseback arrangements.During the nine months ended September 30, 2023, we received $62.1 million of net cash from financing activities, primarily attributable to the $37.9 million in the cash and cash equivalents acquired in connection with the Merger and $30.6 million in proceeds from the issuance of common stock in pre-closing financing, partially offset by $5.8 million in payments of financing costs.Funding RequirementsWe expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct our planned clinical trial of CT-0525, advance our discovery programs and continue our product development efforts. As of September 30, 2024, we had cash and cash equivalents of $26.9 million. We believe that the revised operating plan approved in March 2024 by our board of directors will reduce our spending such that our liquidity is sufficient to sustain our operating expenses and capital expenditure requirements into the third quarter of 2025. As a result, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. We have based our estimate regarding the sufficiency of our cash resources on assumptions that may prove to be wrong, and our revised operating plan may change as a result of many factors currently unknown to us.We expect our expenses to increase substantially over time in connection with our ongoing activities, particularly as we advance our pre-clinical activities and clinical trials. In addition, if we obtain marketing approval for CT-0525 or any other product candidate we are developing or develop in the future, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. In addition, we expect to continue to incur costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise additional capital or obtain adequate funds when needed or on acceptable terms, we may be required to further delay, limit, reduce or terminate our discovery and product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market on our own. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract us from discovery and product development efforts. As a result of the Merger, we acquired Vicineum, a product in development by Sesen Bio for the treatment of non-muscle invasive bladder cancer. On July 15, 2022, Sesen Bio made the strategic decision to voluntarily pause further development of Vicineum in the United States and we have not pursued further development of Vicineum. We have completed the process of unwinding all contractual relationships related to Vicineum.Our future capital requirements will depend on many factors, including:â€¢the progress, costs and results of our ongoing clinical trial of CT-0525 and other planned and future clinical trials;â€¢the scope, progress, costs and results of pre-clinical testing and clinical trials of CT-0525 for additional combinations, targets and indications;27â€¢the number of and development requirements for additional indications for CT-0525 or for any other product candidates;â€¢the success of our collaborations with Moderna or others;â€¢our ability to scale up our manufacturing processes and capabilities to support clinical trials of CT-0525 and other product candidates we are developing and develop in the future;â€¢the costs, timing and outcome of regulatory review of CT-0525 and other product candidates we are developing and may develop in the future;â€¢potential changes in the regulatory environment and enforcement rules;â€¢our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;â€¢the payment of license fees and other costs of our technology license arrangements;â€¢the costs and timing of future commercialization activities, including product manufacturing, sales, marketing and distribution, for CT-0525 and other product candidates we are developing and may develop in the future for which we may receive marketing approval;â€¢our ability to obtain and maintain acceptance of any approved products by patients, the medical community and third-party payors;â€¢the amount and timing of revenue, if any, received from commercial sales of CT-0525 and any other product candidates we are developing or develop in the future for which we receive marketing approval;â€¢potential changes in pharmaceutical pricing and reimbursement infrastructure;â€¢the availability of raw materials for use in production of our product candidates;â€¢the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims; andâ€¢the extent to which we in-license or acquire additional technologies or product candidates.Identifying potential product candidates and conducting pre-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. We will not generate commercial revenues unless and until we can achieve sales of products, which we do not anticipate for a number of years, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. For example, market volatility resulting from general U.S. or global economic or market conditions, including related to any health epidemics, pandemics or other contagious outbreaks, could also adversely impact our ability to access capital as and when needed. Alternatively, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.Until such time, if ever, we can generate substantial revenues from product sales, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. 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 those securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Debt financing and preferred equity financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our operations and ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments, declaring dividends or other operating restrictions that could adversely impact our ability to conduct business.If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, discovery programs or product candidates, grant licenses on terms that may not be favorable to us or grant rights to develop and market product candidates that we would otherwise prefer to develop and market on our own, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be required to further delay, limit, reduce or terminate our discovery and product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market on our own.28Contractual Obligations and CommitmentsThe following table summarizes our contractual obligations and commitments at September 30, 2024 (in thousands):TotalLessthan1 Year1 to 3Years4 to 5YearsMorethan5 YearsContractual obligations:Â Â Â Â Â Operating lease commitments(1)$2,431Â $1,493Â $455Â $483Â $â€”Â Finance lease commitments1,233Â 1,136Â 97Â â€”Â â€”Â Total contractual obligations$3,664Â $2,629Â $552Â $483Â $â€”Â (1)Reflects obligations pursuant to our office and laboratory leases in Philadelphia, Pennsylvania.The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. Our contracts with CMOs, CROs and other third parties for the manufacture of our product candidates and to support pre-clinical research studies and clinical testing are generally cancellable by us upon prior notice and do not contain any minimum purchase commitments. Payments due upon cancellation consisting only of payments for services provided or expenses incurred, including noncancellable obligations of our service providers, up to the date of cancellation are not included in the table above as the amount and timing of such payments are not known.The table above does not include any potential milestone or royalty payments that we may be required to make under our license agreement with Penn and under licensing agreements with other third parties not considered material. We excluded these milestone and royalty payments given that the timing and likelihood of any such payments cannot be reasonably estimated at this time.Critical Accounting Policies and EstimatesOur managementâ€™s discussion and analysis of financial condition and results of operations is based on our unaudited interim consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of our unaudited interim consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our unaudited interim consolidated financial statements. We base our estimates on our limited historical experience, known trends and events and various other factors that we believe are 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 or conditions.During the nine months ended September 30, 2024, there were no material changes to our critical accounting policies and estimates from those described under the heading â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ in our Annual Report on Form 10-K filed with the SEC on April 1, 2024.Recent Accounting PronouncementsSee Note 3 to our unaudited interim consolidated financial statements found in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements.Item 3. Quantitative and Qualitative Disclosures About Market

Risk.We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash, cash equivalents and marketable securities. Interest income earned on these assets was $1.9Â million and $2.7 million for the nine months ended September 30, 2024 and 2023, respectively. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates.29Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended September 30, 2024 and 2023.Item 4. Controls and Procedures.Evaluation of Disclosure Controls and ProceduresOur management, with the participation of our principal executive officer and our principal financial officer have evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of SeptemberÂ 30, 2024. The term â€œdisclosure controls and procedures,â€ as defined in the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SECâ€™s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Companyâ€™s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.Based on the evaluation of our disclosure controls and procedures as of SeptemberÂ 30, 2024, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.Changes in Internal Control over Financial ReportingNo changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended SeptemberÂ 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.30PART IIâ€“OTHER INFORMATIONItem 1. Legal Proceedings.From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. As of the date of this Quarterly Report on Form 10-Q, we were not a party to any material legal matters or claims.Item 1A. Risk Factors.Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors set forth below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and the section of this Quarterly Report on Form 10-Q titled â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ before deciding whether to purchase our securities. The risks and uncertainties we describe below and in the filings mentioned above are not the only ones we face. Additional risks and uncertainties not presently known to us could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment.Summary of Risk Factorsâ€¢We have incurred significant losses since our inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future and may never achieve or maintain profitability.â€¢We will need substantial additional funding for our continuing operations. Attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract from our discovery and product development efforts. If we are unable to raise additional capital when needed or on acceptable terms, we could be forced to further delay, reduce or eliminate some or all of our discovery or product development programs or commercialization efforts.â€¢We have never generated revenue from product sales and may never achieve or maintain profitability.â€¢Our reduction in force undertaken to extend our cash runway and focus our resources on our prioritized research and development programs might not achieve our intended outcome.â€¢We are heavily dependent on the success of our lead product candidate, CT-0525, which will require significant clinical testing before we can seek marketing approval and potentially generate commercial sales. If CT-0525 does not receive marketing approval or is not successfully commercialized, or if there is significant delay in doing so, our business will be harmed.â€¢Cell therapy is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates by utilizing genetically modified macrophages is novel and may never lead to approved or marketable products.â€¢We have and may in the future curtail, pause, delay or cease development of a product candidate at any stage of pre-clinical or clinical development based on a variety of factors, including our judgments regarding costs or timing of further development, probability of success of clinical development (including because of a decrease in the pool of available patients), regulatory requirements, commercial potential, relative benefits and costs compared to other product candidates in our portfolio, and our overall corporate strategy.â€¢Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of our product candidates, if approved, may be smaller than we estimate.â€¢We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may prevent or delay our ability to seek or obtain marketing approval for or commercialize our product candidates or otherwise harm our business. If we are not able to maintain these third-party relationships or if these arrangements are terminated, we may have to alter our development and commercialization plans and our business could be adversely affected.â€¢We rely, and expect to continue to rely, on third parties to manufacture our drug substance and drug product, and those third parties may not perform satisfactorily, including failing to meet deadlines to provide adequate drug product for our clinical trials. This may prevent or delay our ability to complete our clinical trials and to seek or obtain marketing approval for or commercialize our product candidates or otherwise harm our business. If we are not able to maintain these third-party relationships or if these arrangements are terminated, we may have to alter our development and commercialization plans and our business could be adversely affected.31â€¢We currently, and may in the future, rely on single-source suppliers for certain materials and components used in the manufacturing of our product candidates. Any disruption in supply from these single-source suppliers could lead to supply delays or interruptions which would materially adversely affect our business, financial condition and results of operations. â€¢If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected and we may not be able to compete effectively in our market.â€¢The regulatory approval process of the FDA is lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed. â€¢The market price of our common stock may be volatile, and the market price of our common stock may drop in the future. â€¢We incur and will continue to incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.â€¢If at some point we are no longer a â€œsmaller reporting companyâ€ or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results. Risks Related to Our Financial Position and Need for Additional CapitalWe have incurred significant losses since our inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future and may never achieve or maintain profitability. Since inception, we have incurred significant operating losses. Our net losses were $12.7 million and $21.4 million for the three months ended September 30, 2024 and 2023, respectively. To date, we have not yet commercialized any products or generated any revenue from product sales and have financed our operations primarily with proceeds from sales of our preferred stock, proceeds from our collaboration with Moderna, research tax credits and convertible debt financing. We have devoted substantially all of our financial resources and efforts to pursuing discovery, research and early clinical development of our product candidates. We are in the early stages of development of our lead product candidate, CT-0525. We treated the first patient in the Phase 1 clinical trial of CT-0525 in May 2024 and received Fast Track designation from the FDA in June 2024.We expect to continue to incur significant expenses and operating losses for the foreseeable future, including costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:â€¢enhance the capabilities of our CAR-M platform;â€¢continue to conduct a clinical trial of CT-0525 for solid tumors that overexpress HER2;â€¢conduct discovery and pre-clinical testing of the development of in vivo CAR-M therapeutics for up to twelve research targets, as well as multiple other targets and indications;â€¢conduct discovery and pre-clinical testing of our autologous cell therapy pipeline to gather information to apply to the development of off-the-shelf engineered macrophage therapeutics;â€¢develop iPSC-derived CAR-M, and other macrophage therapies;â€¢develop in vivo reprogrammed mRNA/LNP CAR-M therapies for cancer;â€¢develop viral vectors to effectively engineer human monocytes and macrophages, including the Vpx lentiviral vector and our Ad5f35 vector;â€¢conduct discovery and pre-clinical testing of our other product candidates, including those in our fibrosis program;â€¢seek marketing approval for CT-0525 or any other product candidate if we successfully complete clinical trials;â€¢scale up our external manufacturing capabilities and capabilities to support clinical trials of CT-0525 or any other of our product candidates and for commercialization of any product candidate for which we may obtain marketing approval;â€¢establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;â€¢in-license or acquire additional technologies or product candidates;â€¢make any payments under our existing or future strategic collaboration agreements, global exclusive rights licensing agreements or sponsored research agreements, including with Moderna;â€¢maintain, expand, enforce and protect our intellectual property portfolio;â€¢hire additional clinical, regulatory, manufacturing, quality control, development and scientific personnel; and32â€¢add operational, financial and management information systems and personnel, including personnel to support our discovery, product development and planned future commercialization efforts and our operations as a public company.Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond our expectations if, among other things:â€¢we are required by regulatory authorities in the United States, Europe, or other jurisdictions to perform trials or studies in addition to, or different than, those that we currently expect;â€¢there are any delays in establishing appropriate manufacturing arrangements for or completing the development of any of our product candidates; orâ€¢there are any third-party challenges to our intellectual property or our needs to defend against any intellectual property-related claim.Even if we obtain marketing approval for and are successful in commercializing one or more of our product candidates, we expect to incur substantial additional discovery and product development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. We have never generated revenue from product sales and may never achieve or maintain profitability.We recently initiated clinical development of our lead product candidate, CT-0525 and have completed all remaining clinical activities under our Phase 1 clinical trial of CT-0508, which we do not plan to develop further at this time. We are in the pre-clinical testing stages for our other product candidates. We expect that it will be a number of years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must succeed in completing development of, obtaining marketing approval for and eventually commercializing, one or more products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including completing clinical development of CT-0525, completing discovery, pre-clinical testing and clinical development of CT-0525 in the combination setting and for potential additional indications, timely filing and receiving acceptance of our IND applications, in order to commence our planned or future clinical trials, successfully enrolling subjects in, and completing, our ongoing and planned clinical trials, scaling up our manufacturing processes and capabilities to support clinical trials of CT-0525 or of other product candidates, obtaining marketing approval for CT-0525 or any other product candidates, manufacturing, marketing and selling any products for which we may obtain marketing approval and

maintaining a continued acceptable safety profile of our products following approval. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability.Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our discovery and product development efforts, diversify our pipeline of product candidates or even continue our operations.We are heavily dependent on the success of our lead product candidate, CT-0525, which will require significant clinical testing before we can seek marketing approval and potentially generate commercial sales. If CT-0525 does not receive marketing approval or is not successfully commercialized, or if there is significant delay in doing so, our business will be harmed.We initiated our first clinical trial in 2020, have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures for the foreseeable future will be devoted to CT-0525 and related combination sub-studies, including CT-0525 in combination with pembrolizumab or another checkpoint inhibitor. Our business currently depends heavily on the successful development, marketing approval and commercialization of CT-0525, and the success of related combination sub-studies. We cannot be certain that CT-0525 or any combination therapy involving CT-0525 will achieve success in ongoing or future clinical trials, receive marketing approval or be successfully commercialized.If we were required to discontinue development of CT-0525, or if CT-0525 does not receive marketing approval for one or more of the indications we pursue, fail to achieve significant market acceptance, or fail to receive adequate reimbursement, 33we may be delayed by many years in our ability to achieve profitability, if ever, and may not be able to generate sufficient revenue to continue our business.We will need substantial additional funding for our continuing operations. If we are unable to raise additional capital on acceptable terms, we could be forced to further delay, reduce or eliminate our discovery or product development programs or commercialization efforts.We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct our ongoing clinical trial of CT-0525 and pursue related combination strategies, prepare for, initiate and conduct clinical trials of other product candidates, advance our discovery programs and continue our product development efforts. We expect our expenses to increase substantially over time in connection with our ongoing activities, particularly as we advance our pre-clinical activities and clinical trials. In addition, if we obtain marketing approval for CT-0525 or any other product candidate we are developing or develop in the future, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we will incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise additional capital or obtain adequate funds on acceptable terms, we may be required to further delay, limit, reduce or terminate our discovery and product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract from our discovery and product development efforts.Our future capital requirements will depend on many factors, including:â€¢the progress, costs and results of our clinical trials of CT-0525 and other planned and future clinical trials;â€¢the scope, progress, costs and results of pre-clinical testing and clinical trials of CT-0525 for additional combinations, targets and indications;â€¢the scope, progress, costs and results of pre-clinical testing of product candidates in our fibrosis program;â€¢the number of and development requirements for additional indications for CT-0525 or for any other product candidates;â€¢the success of our collaborations with Moderna or others;â€¢our ability to scale up our manufacturing processes and capabilities to support clinical trials of CT-0525 and other product candidates we are developing and develop in the future;â€¢the costs, timing and outcome of regulatory review of CT-0525 and other product candidates we are developing and may develop in the future;â€¢potential changes in the regulatory environment and enforcement rules;â€¢our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;â€¢the payment of license fees and other costs of our technology license arrangements;â€¢the costs and timing of future commercialization activities, including product manufacturing, sales, marketing and distribution, for CT-0525 and other product candidates we are developing and may develop in the future for which we may receive marketing approval;â€¢our ability to obtain and maintain acceptance of any approved products by patients, the medical community and third-party payors;â€¢the amount and timing of revenue, if any, received from commercial sales of CT-0525 and any other product candidates we are developing or develop in the future for which we receive marketing approval;â€¢potential changes in pharmaceutical pricing and reimbursement infrastructure;â€¢the availability of raw materials for use in production of our product candidates;â€¢the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims; andâ€¢the extent to which we in-license or acquire additional technologies or product candidates.As of SeptemberÂ 30, 2024, we had cash and cash equivalents of $26.9 million that we believe are sufficient to sustain our planned operations and capital expenditure requirements into the third quarter of 2025. However, we have based this estimate on assumptions that may prove to be wrong, and our revised operating plan may change as a result of many factors currently unknown to us. In addition, changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. As a result, we could deplete our capital resources sooner than we currently expect. In addition, because the successful development of CT-0525 and any combination studies or other product candidates that we pursue is highly 34uncertain, at this time we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any product candidate. Identifying potential product candidates and conducting pre-clinical and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. We will not generate commercial revenues unless and until we can achieve sales of products, which we do not anticipate for a number of years, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and we may be impacted by the economic climate and market conditions. For example, market volatility resulting from general U.S. or global economic or market conditions, including related to any health epidemics, pandemics or other contagious outbreaks, could also adversely impact our ability to access capital as and when needed. Alternatively, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.We were formed as Carma Therapeutics LLC, a Pennsylvania limited liability company, in April 2016 and converted to a Delaware corporation in May 2017 under the name CARISMA Therapeutics Inc. In connection with the Merger consummated in March 2023, CARISMA Therapeutics Inc. merged with and into a wholly-owned subsidiary of Sesen Bio and was renamed â€œCTx Operations, Inc.â€ Sesen Bio's name was changed to â€œCarisma Therapeutics Inc.â€ Following the completion of the Merger, the business conducted by the public company became primarily the business conducted by us. We are a clinical-stage cell therapy company with a limited operating history. Cell therapy product development is a highly speculative undertaking and involves a substantial degree of risk. Our operations prior to the Merger have been limited to organizing and staffing the Company, business planning, capital raising, establishing and maintaining our intellectual property portfolio, building our pipeline of product candidates, conducting drug discovery activities, undertaking pre-clinical studies, manufacturing process development studies, conducting early-stage clinical trials, and providing general and administrative support for these operations. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have not yet demonstrated our ability to successfully develop any product candidate, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing products.In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We will need to transition at some point from a company with a discovery and pre-clinical and clinical focus to a company capable of supporting commercial activities. We may not be successful in such a transition.As we continue to build our business, we expect our financial condition and operating results to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.Changes in tax law may adversely affect us or our investors.The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholdersâ€™ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Prospective investors should consult their tax advisors regarding the potential consequences of changes in tax law on our business and on the ownership and disposition of our common stock.35Our ability to use our NOLs and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.Prior to the Merger, we had a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future. As a result, we do not know whether or when we will generate taxable income necessary to utilize our NOLs or research and development tax credit carryforwards. In general, under Section 382 of the Code and corresponding provisions of state law, a corporation that undergoes an â€œownership change,â€ generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period, is subject to limitations on our ability to utilize our pre-change NOLs and research and development tax credit carryforwards to offset future taxable income. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past and may experience such ownership changes in the future (which may be outside our control). As a result, if and to the extent we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.Risks Related to Our Discovery Programs and Research and Development of Our Product CandidatesCell therapy is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates by utilizing genetically modified macrophages and monocytes is novel and may never lead to approved or marketable products.Cell therapy has yet to be broadly applied to solid tumors, inflammatory disease, fibrotic disease or neurodegeneration. The discovery, research and development of engineered macrophages and monocytes to treat disease is an emerging field and our CAR-M platform, which is the first CAR-M to be evaluated in a human clinical trial, is a relatively new technology. Our future success depends on the successful development of this novel therapeutic approach. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. As such, there may be adverse effects or limited favorable results from treatment with any of our current or future product candidates that we cannot predict at this time.Our success also depends on our successful application of our proprietary macrophage engineering platform in the combination setting and to other indications by reprogramming the target specificity of our CAR-M cell product and developing product candidates against a plethora of tumor associated antigens, including in therapeutic areas beyond oncology. However, our macrophage engineering platform may not allow us to generate new INDs to expand our pipeline on our anticipated timeline or in a cost-efficient manner or at all, which could cause the potential value of our business to decline and materially harm our business prospects.As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of macrophage engineering platform will result in the development and marketing approval of any products. Any development problems we experience in the future related to our macrophage engineering platform or any of our discovery programs may cause significant delays or unanticipated costs

or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our clinical trials or pre-clinical studies or commercializing any product candidates we may develop on a timely or profitable basis, if at all.We are early in our development efforts. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.We are early in our development efforts. We initiated our first Phase 1 clinical trial in 2020. We received a Study May Proceed notification from the FDA for CT-0525 in November 2023, treated our first patient in our Phase 1 clinical trial in May 2024 and received Fast Track designation from the FDA in June 2024. We expect to report initial data from the clinical trial in the first quarter of 2025.Our ability to generate revenues from product sales, which we do not expect will occur for a number of years, if ever, will depend heavily on the successful development, marketing approval and eventual commercialization of CT-0525, including in the combination setting, or one or more of our other product candidates, which may never occur. The success of CT-0525 and our other product candidates will depend on many factors, including the following:â€¢successfully completing pre-clinical studies;36â€¢successfully initiating future clinical trials;â€¢successfully enrolling patients in our Phase 1 clinical trial of CT-0525 and completing clinical trials;â€¢scaling up manufacturing processes and capabilities to support clinical trials of CT-0525 and any other product candidate;â€¢applying for and receiving marketing approvals from applicable regulatory authorities;â€¢obtaining and maintaining intellectual property protection and regulatory exclusivity for CT-0525 and any other product candidates we are developing or may develop in the future;â€¢making arrangements with third-party manufacturers, or establishing commercial manufacturing capabilities, for both clinical and commercial supplies of our product candidates;â€¢establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;â€¢acceptance of CT-0525 and any other product candidates, if and when approved, by patients, the medical community and third-party payors;â€¢effectively competing with other therapies;â€¢obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;â€¢maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;â€¢not infringing, misappropriating or otherwise violating othersâ€™ intellectual property or proprietary rights; andâ€¢maintaining a continued acceptable safety profile of our products following receipt of any marketing approvals.If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially harm our business. As a company, we have limited experience in clinical development. Any predictions about the future success or viability of CT-0525 or any product candidates we are developing or may develop in the future may not be as accurate as they could be if we had a history of conducting clinical trials.Drug development involves a lengthy and expensive process, with an uncertain outcome. The results of pre-clinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of CT-0525 or our other product candidates.We dosed the first patient in our Phase 1 clinical trial of CT-0525 in May 2024. Our other product candidates, including those in our fibrosis program, are in pre-clinical development. The risk of failure for CT-0525 and our other product candidates is high. It is impossible to predict when or if CT-0525 or any of our other product candidates will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of a product candidate, we must complete pre-clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidate in humans. Clinical trials may fail to demonstrate that CT-0525 or any of our other product candidates are safe for humans and effective for indicated uses. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.Before we can commence clinical trials for a product candidate, we must complete extensive pre-clinical testing and studies, manufacturing process development studies, and analytical development studies that support our planned INDs and other applications to regulatory authorities in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our pre-clinical testing and studies and cannot predict if the outcome of our pre-clinical testing and studies will ultimately support the further development of our current or future product candidates or whether regulatory authorities will accept our proposed clinical programs. As a result, we may not be able to submit applications to initiate clinical development of product candidates on the timelines we expect, if at all, and the submission of these applications may not result in regulatory authorities allowing clinical trials to begin. Furthermore, product candidates are subject to continued pre-clinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. We cannot guarantee that any of our clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, 37including, among other things, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates or cause regulatory authorities to require additional testing before approving any of our product candidates.We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates, including:â€¢regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or at all;â€¢we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;â€¢regulators may determine that the planned design of our clinical trials is flawed or inadequate;â€¢clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;â€¢we may be unable to establish clinical endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities consider likely to predict clinical benefit;â€¢pre-clinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional pre-clinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trials or abandon product development programs;â€¢the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate (including because of a decrease in the pool of available patients) or participants may drop out of these clinical trials at a higher rate than we anticipate;â€¢third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;â€¢we may decide, or regulators or IRBs may require us, to suspend or terminate clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;â€¢regulators or IRBs may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain marketing approval;â€¢regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;â€¢the cost of clinical trials of our product candidates may be greater than we anticipate;â€¢the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;â€¢our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our clinical investigators, regulators or IRBs to suspend or terminate the trials;â€¢regulators may withdraw their approval of a product or impose restrictions on its distribution; andâ€¢business interruptions resulting from any health epidemics, pandemics or other contagious outbreaks may result in adverse effects on our business and operations.If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may:â€¢incur unplanned costs;â€¢be delayed in obtaining marketing approval for our product candidates;â€¢not obtain marketing approval at all;â€¢obtain marketing approval in some countries and not in others;â€¢obtain approval for indications or patient populations that are not as broad as intended or desired;â€¢obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;â€¢be subject to additional post-marketing testing requirements; or38â€¢have the product removed from the market after obtaining marketing approval.Our product development costs will also increase if we experience delays in pre-clinical studies or clinical trials or in obtaining marketing or other regulatory approvals. We do not know whether any of our pre-clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses or delays. Significant pre-clinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.In addition, the FDAâ€™s and other regulatory authoritiesâ€™ policies with respect to clinical trials may change and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of the Food and Drug Omnibus Reform Act of 2022, or FDORA, Congress required sponsors to develop and submit a diversity action plan, or DAP, for each phase 3 clinical trial or any other â€œpivotal studyâ€ of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, DAPs must include the sponsorâ€™s goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.Similarly, the regulatory landscape related to clinical trials in the European Union recently evolved. The EU Clinical Trials Regulation, or the EU-CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate Clinical Trial Application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the EU-CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The EU-CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member stateâ€™s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. If we are not able to adapt to these and other changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.Further, cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for second-line or third-line use. When cancer is detected early enough, first-line therapy, usually hormone therapy, surgery, radiation therapy, chemotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. For any of our products that prove to be sufficiently beneficial, we would expect to seek approval potentially as a first-line therapy, but any product candidates we develop, even if approved, may not be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.We may

conduct clinical trials at sites outside the United States. The FDA may not accept data from trials conducted in such locations, and the conduct of trials outside the United States could subject us to additional delays and expense. We may conduct one or more clinical trials with one or more trial sites that are located outside the United States. The acceptance by the FDA or other regulatory authorities of study data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant good clinical practices, or to GCP, regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted 39in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.Conducting clinical trials outside the U.S. also exposes us to additional risks, including risks associated with: â€¢additional foreign regulatory requirements; â€¢foreign exchange fluctuations; â€¢compliance with foreign manufacturing, customs, shipment and storage requirements; â€¢cultural differences in medical practice and clinical research; â€¢diminished protection of intellectual property in some countries; and â€¢interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.The results of early-stage clinical trials and pre-clinical studies may not be predictive of future results. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. In particular, the small number of patients in our ongoing or future early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. For example, even if successful, the results of our Phase 1 clinical trial of CT-0525 may not be predictive of the results of further clinical trials of CT-0525 or any of our other product candidates. Our product candidates may also fail to show the desired safety and efficacy in clinical development despite positive results in pre-clinical studies or having successfully advanced through initial clinical trials.Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Our current or future clinical trials may not ultimately be successful or support further clinical development of any of our product candidates and we cannot assure you that any clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to support marketing approval. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials even after achieving promising results in pre-clinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Any such setbacks in our clinical development could materially harm our business and results of operations.Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures, which could result in material changes in the final data.From time to time, we may announce or publish interim 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 participant enrollment continues and more participant data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary or interim 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. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common stock to fluctuate significantly.40If we experience delays or difficulties in the enrollment of patients in our clinical trials for CT-0525 or any of our other product candidates, our receipt of necessary marketing approvals could be delayed or prevented.Identifying and qualifying patients to participate in our clinical trial for CT-0525 and any other product candidates in the future is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the trial until its conclusion. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. In particular, our clinical trial of CT-0525 is open for enrollment and the first patient was treated in May 2024. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitorsâ€™ product candidates. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Patient enrollment is affected by a variety of other factors, including:â€¢the prevalence and severity of the disease under investigation;â€¢the eligibility criteria for the trial in question;â€¢the perceived risks and benefits of the product candidate under trial;â€¢the requirements of the trial protocols;â€¢the availability of existing treatments for the indications for which we are conducting clinical trials;â€¢the ability to recruit clinical trial investigators with the appropriate competencies and experience;â€¢the efforts to facilitate timely enrollment in clinical trials;â€¢the ability to identify specific patient populations based on specific genetic mutations or other factors;â€¢the patient referral practices of physicians;â€¢the ability to monitor patients adequately during and after treatment;â€¢our ability to obtain and maintain patient consents;â€¢the proximity and availability of clinical trial sites for prospective patients;â€¢the conduct of clinical trials by competitors for product candidates that treat the same indications or address the same patient populations as our product candidates;â€¢the cost to, or lack of adequate compensation for, prospective patients; andâ€¢the impact of any health epidemics, pandemics or other contagious outbreaks.Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary marketing approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our business to decline and limit our ability to obtain additional financing.If serious adverse events, undesirable side effects or unexpected characteristics are identified during the development of CT-0525 or any of our other product candidates, we may need to abandon or limit our further clinical development of those product candidates.Our Phase 1 clinical trial of CT-0525 is open for enrollment and the first patient was treated in May 2024. If CT-0525 or any other product candidate is associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected in clinical trials or pre-clinical testing, we may need to abandon development of such product candidate or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or unexpected characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In pharmaceutical development, many compounds that initially show promise in early-stage or clinical testing are later found to cause side effects that delay or prevent further development of the compound or decrease the size of the patient population for whom the compound could ultimately be prescribed. For example, while CT-0508 has been generally well tolerated based on the preliminary and limited clinical results from our Phase 1 clinical trial, such results may not be predictive or indicative of the preliminary clinical results from our Phase 1 clinical trial of our lead product candidate, CT-0525, or the successful development, marketing approval and eventual commercialization of CT-0525.Additionally, if results of our clinical trials reveal undesirable side effects, we, regulatory authorities or the IRBs at the institutions in which our studies are conducted could suspend or terminate our clinical trials, regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications or we could be forced to materially modify the design of our clinical trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff.41If we elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate revenues from sales of such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business.If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.We initiated our Phase 1 clinical trial of CT-0525 and the first patient was treated in May 2024. We are in the pre-clinical testing stages for our other product candidates. Clinical trials will be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives marketing approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:â€¢withdrawal or limitation by regulatory authorities of approvals of such product;â€¢seizure of the product by regulatory authorities;â€¢recall of the product;â€¢restrictions on the marketing of the product or the manufacturing process for any component thereof;â€¢requirement by regulatory authorities of additional warnings on the label;â€¢requirement that we implement a risk evaluation and mitigation strategy or create a medication guide outlining the risks of such side effects for distribution to patients;â€¢commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;â€¢the product may become less competitive;â€¢initiation of regulatory investigations and government enforcement actions;â€¢initiation of legal action against us to hold us liable for harm caused to patients; andâ€¢harm to our reputation and resulting harm to physician or patient acceptance of our products.Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.Because we have limited financial and managerial resources, we focus on discovery programs and product candidates that we identify for specific indications. As a result, we have and may in the future forego or delay the pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. In late March 2024, we determined to focus our ex vivo oncology clinical development efforts on our lead product candidate CT-0525, cease further development of CT-0508, and pause further development of CT-1119 for expense reduction purposes. We may further curtail, pause, delay or cease development of other product candidates at any stage of pre-clinical or clinical development based on a variety of factors, including our judgments regarding costs or timing of further development, probability of success of clinical development, regulatory requirements, commercial potential, relative benefits and costs compared to other product candidates in our portfolio, and our overall corporate strategy. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and product development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to

such product candidate. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business.We are considering expanding our Phase 1 clinical trial of CT-0525 to include its evaluation in combination with pembrolizumab or another checkpoint inhibitor and we may also evaluate CT-0525 in combination with other drugs. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs, revoke their 42approval of such drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with CT-0525, we may be unable to obtain approval of CT-0525 or market CT-0525.We initiated our Phase 1 clinical trial of CT-0525 and the first patient was treated in May 2024. We are considering expanding this trial to evaluate CT-0525 in combination with pembrolizumab or another checkpoint inhibitor and may also evaluate CT-0525 in combination with other drugs in the future.We did not develop or obtain marketing approval for, nor have we manufactured or sold, any of the currently approved drugs that we may study in combination with CT-0525. If the FDA or similar regulatory authorities outside of the United States revoke their approval of any drug or drugs in combination with which we determine to develop CT-0525, we will not be able to market CT-0525 in combination with such revoked drugs.If safety or efficacy issues arise with any of these drugs, we could experience significant regulatory delays, and the FDA or similar regulatory authorities outside of the United States may require us to redesign or terminate the applicable clinical trials. If the drugs we use are replaced as the standard of care for the indications we choose for CT-0525, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. In addition, if manufacturing or other issues result in a shortage of supply of the drugs with which we determine to combine with CT-0525, we may not be able to complete clinical development of CT-0525 on our current timeline or at all.Even if CT-0525 were to receive marketing approval or be commercialized for use in combination with other existing drugs, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the drugs used in combination with CT-0525 or that safety, efficacy, manufacturing or supply issues could arise with these existing drugs. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our other product candidates for use in combination with other drugs for cancer or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.We may not be successful in our efforts to identify or discover additional potential product candidates.A key element of our strategy is to apply our macrophage engineering platform to address a broad array of indications and targets to generate next-generation therapeutics, including programs for indications outside of oncology. The discovery efforts that we are conducting may not be successful in identifying product candidates that are useful in treating cancer or other diseases. Our discovery engine may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:â€¢potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval or achieve market acceptance; orâ€¢potential product candidates may not be effective in treating their targeted diseases.Discovery programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. If we are unable to identify additional suitable product candidates for pre-clinical and clinical development, it will limit our potential to obtain revenues from sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.Adverse public perception of genetic medicine, and gene therapy in particular, may negatively impact regulatory approval of, or demand for, our potential products.The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy is unsafe, unethical, or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates that we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.43Risks Related to the Commercialization of Our Product CandidatesEven if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of our product candidates, if approved, may be smaller than we estimate.If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments, such as chemotherapy and radiation therapy, are well established in the medical community and doctors may continue to rely on these and similar treatments. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenues from product sales and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:â€¢the efficacy and potential advantages of our product candidates compared to the advantages and relative risks of alternative treatments;â€¢the effectiveness of sales and marketing efforts;â€¢our ability to offer our products, if approved, for sale at competitive prices;â€¢the clinical indications for which the product is approved;â€¢the cost of treatment in relation to alternative treatments;â€¢the convenience and ease of administration compared to alternative treatments;â€¢the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;â€¢the strength of marketing and distribution support;â€¢the timing of market introduction of competitive products;â€¢the availability of third-party coverage and adequate reimbursement, and patientsâ€™ willingness to pay out of pocket for required co-payments or in the absence of third-party coverage or adequate reimbursement;â€¢product labeling or product insert requirements of the FDA, the European Medical Agency, or the EMA, or other regulatory authorities, including any limitations or warnings contained in a productâ€™s approved labeling;â€¢the prevalence and severity of any side effects;â€¢support from patient advocacy groups; andâ€¢any restrictions on the use of our products, if approved, together with other medications.Our assessment of the potential market opportunity for our product candidates is based on industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and our analysis of these data, research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for any of our product candidates may be smaller than we expect, and as a result our revenues from product sales may be limited and it may be more difficult for us to achieve or maintain profitability.If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates if and when they are approved.We do not have a sales or marketing infrastructure and have no experience as a company in the sale, marketing or distribution of biopharmaceutical products. To achieve commercial success for any product for which we may obtain marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties.We currently expect that we would build our own focused, specialized sales and marketing organization to support the commercialization in the United States of product candidates for which we receive marketing approval and that can be commercialized with such capabilities. There are risks involved with us establishing our own sales, marketing and 44distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In general, the cost of establishing and maintaining a sales and marketing organization may exceed the cost-effectiveness of doing so.Factors that may inhibit our efforts to commercialize our products on our own include:â€¢our inability to recruit, train and retain adequate numbers of effective sales, marketing, market access, distribution, customer service, medical affairs and other support personnel;â€¢our inability to equip sales personnel with effective materials;â€¢our inability to effectively manage a geographically dispersed sales and marketing team;â€¢the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;â€¢the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;â€¢the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;â€¢restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;â€¢the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; andâ€¢unforeseen costs and expenses associated with creating an independent commercialization organization.If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our revenues from product sales and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do, thus rendering our products non-competitive, obsolete or reducing the size of the market for our products.The biopharmaceutical industry, and in particular the cell therapy field, is characterized by intense investment and competition aimed at rapidly advancing new technologies. Our platform and therapeutic product candidates are expected to face substantial competition from multiple technologies, marketed products and numerous other therapies being developed by third parties that use protein degradation, antibody therapy, inhibitory nucleic acid, gene editing or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. The competition is likely to come from multiple sources, including biopharmaceutical companies, academic research institutions, governmental agencies and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. The competition is likely to come from multiple sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research institutions.We are aware of a number of companies generally pursuing the development of myeloid cell therapies, including, among others Myeloid Therapeutics, Shoreline Biosciences, Inceptor Bio, Thunder Bio, Resolution Therapeutics, CellOrigin, SIRPant Therapeutics, and others. We are also facing competition from companies pursuing autologous T cell therapies, allogeneic T cell therapies, NK and other cell therapies, direct in vivo reprogrammed cell therapies and other macrophage-targeted oncology therapeutics.Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. These competitors also 45compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are

more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.Technology in the biopharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development.Mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.We have pursued and may in the future pursue the in-license or acquisition of rights to complementary technologies and product candidates on an opportunistic basis. However, we may be unable to in-license or acquire any additional technologies or product candidates from third parties. The acquisition and licensing of technologies and product candidates is a competitive area, and a number of more established companies also have similar strategies to in-license or acquire technologies and product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater 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 in-license or acquire the relevant technology or product candidate on terms that would allow us to make an appropriate return on our investment.Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. The availability of coverage and adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products, including our product candidates. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. 46Increasingly, government authorities and third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers its costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.There can be no assurance that our product candidates, even if they are approved for sale in the United States, in the European Union or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payorsâ€™ reimbursement policies will not adversely affect our ability to sell our product candidates profitably.Clinical trial and product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.We face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. While we currently have no products that have been approved for commercial sale, the ongoing, planned and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:â€¢decreased demand for any product candidates or products that we may develop;â€¢termination of clinical trials;â€¢withdrawal of marketing approval, recall, restriction on the approval or a â€œblack boxâ€ warning or contraindication for an approved drug;â€¢withdrawal of clinical trial participants;â€¢significant costs to defend any related litigation;â€¢substantial monetary awards to trial participants or patients;47â€¢loss of revenue;â€¢injury to our reputation and significant negative media attention;â€¢reduced resources of our management to pursue our business strategy;â€¢distraction of managementâ€™s attention from our primary business; andâ€¢the inability to commercialize any products that we may develop.We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.Risks Related to Our Dependence on Third PartiesWe rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may prevent or delay our ability to seek or obtain marketing approval for or commercialize our product candidates or otherwise harm our business. If we are not able to maintain these third-party relationships or if these arrangements are terminated, we may have to alter our development and commercialization plans and our business could be adversely affected.We rely, and expect to continue to rely, on third-party clinical research organizations, in addition to other third parties such as research collaboratives, clinical data management organizations, medical institutions and clinical investigators, to conduct our Phase 1 clinical trial of CT-0525 and any other clinical trials we conduct. We currently have no plans to independently conduct clinical trials of our product candidates or any other product candidates that we may develop. These CROs, and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. These third-party arrangements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities might be delayed.Our reliance on these third parties for discovery and product development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities in Europe and other jurisdictions have similar requirements. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit to the FDA. Any such delay or rejection could prevent

us from commercializing our product candidates.If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding more CROs, investigators and other third 48parties 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 can occur, which could materially impact our ability to meet our desired clinical development timelines. Although we plan to carefully manage our relationships with our CROs, investigators and other third parties, we may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, financial condition and prospects.We rely on third-party CMOs for the manufacture of both drug substance and finished drug product of our product candidates for pre-clinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third-party CMOs for both drug substance and finished drug product, as well as for commercial manufacture if any of our product candidates receive marketing approval. We also currently rely on these third parties for the manufacture of plasmid and viral vectors, patient leukapheresis material logistics, as well as packaging, labeling, sterilization, storage, distribution and other production logistics. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:â€¢reliance on the third party for regulatory compliance and quality assurance;â€¢the possible breach of the manufacturing agreement by the third party;â€¢the potential failure to manufacture our product candidate or product according to our specifications;â€¢the potential failure to manufacture our product candidate or product according to our schedule or at all;â€¢the possible misappropriation of our proprietary information, including our trade secrets and know-how; andâ€¢the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.We or our third-party manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredients necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredients, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredients by our competitors or others. Our or our third-party manufacturers' failure to obtain the raw materials or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business.Our third-party manufacturers are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to ongoing inspection from time to time. Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside of 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 clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If any of our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer. 49Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.We currently, and may in the future, rely on single-source suppliers for certain materials and components used in the manufacturing of our product candidates. We currently, and may in the future, rely on single-source suppliers for certain materials and components used in the manufacturing of our product candidates. There are, for certain of these materials and components, few, if any, alternative sources of supply and there is limited need for multiple suppliers at this stage of our business. We cannot ensure that these suppliers will remain in business, have sufficient capacity or supply to meet our needs, be able to supply materials to us at costs that are acceptable to us, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of certain materials and components exposes us to several risks, including disruptions in supply, price increases or late deliveries. This supplier may be unable or unwilling to meet our future demands for our clinical trials. Establishing additional or replacement suppliers for these materials and components could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from these single-source suppliers could lead to supply delays or interruptions which would materially adversely affect our business, financial condition and results of operations. We expect to depend on collaborations with third parties for the research, development and commercialization of certain of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.We anticipate seeking third-party collaborators for the research, development and commercialization of certain of our product candidates. For example, we entered into a strategic collaboration with Moderna in January 2022 focused on the development of in vivo CAR-M therapeutics for up to twelve research targets. In collaboration with Moderna, we have established a mRNA/LNP in vivo CAR-M platform for research targets, which enables an off-the-shelf approach wherein the patientâ€™s own myeloid cells are engineered directly within their body via the administration of a LNP encapsulating macrophage reprogramming mRNA CAR constructs, removing the requirement for ex vivo cell manufacturing entirely. In June 2024, we announced the nomination of the first Development Candidate under the collaboration with Moderna. The Development Candidate targets GPC3. In September 2024, we expanded the collaboration with Moderna to include two autoimmune targets. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies and biotechnology companies.Any such arrangements with third parties will likely limit our control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaboratorsâ€™ abilities and efforts to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.Collaborations involving our discovery programs or any product candidates we may develop, including our collaboration with Moderna for both oncology and autoimmune targets, pose the following risks to us:â€¢collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations; for example, our collaboration with Moderna is managed by a JSC, which is comprised of representatives from the Company and Moderna, with Moderna having final decision-making authority, subject to specified limitations;â€¢collaborators may not perform their obligations as expected;â€¢collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaboratorsâ€™ strategic focus or available funding, or external factors, such as an acquisition or business combination, that divert resources or create competing priorities;â€¢collaborators may not pursue development and commercialization of any product candidates that achieve marketing approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaboratorsâ€™ strategic focus or available funding, or external factors, such as an acquisition or business combination, that may divert resources or create competing priorities;50â€¢collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;â€¢we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis; for example, data, results and know-how generated in the performance of the Moderna collaboration is deemed the confidential information of Moderna, which we may not disclose except under limited circumstances;â€¢collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;â€¢product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;â€¢a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;â€¢a collaborator may seek to renegotiate or terminate their relationship with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;â€¢a collaborator with marketing and distribution rights to one or more of our product candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such product or products;â€¢disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;â€¢we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;â€¢collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; for example, Moderna has the first right to prosecute, enforce or defend certain patent rights under its agreement with us, and although we may have the right to assume the prosecution, enforcement or defense of such patent rights if Moderna does not, our ability to do so may be compromised by Modernaâ€™s actions;â€¢disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;â€¢collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability;â€¢collaborations may be terminated, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; for example, Moderna has the right to terminate its agreement with us for convenience in its entirety or with respect to a specific product or target on ninety daysâ€™ prior notice, in connection with a material breach of the agreement by us that remains uncured for a specified period of time or in the event of specified insolvency events involving us; andâ€¢collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If a present or future collaborator of ours was to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, or receive it in the timeframe in which we expect to receive it, the development of our product candidates could be delayed, and we may need additional resources to develop our product candidates. All of the risks relating to product development, marketing

approval and commercialization described herein also apply to the activities of our collaborators.We may in the future decide to collaborate with biopharmaceutical companies for the development and potential commercialization of any product candidates we may develop. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our 51existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaboratorâ€™s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaboratorâ€™s evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.We may seek to establish additional collaborations. If we are not able to establish or maintain additional collaborations, on commercially reasonable terms, we may have to alter our development and commercialization plans, and our business could be adversely affected.To realize the full potential of our macrophage engineering platform and accelerate the development of additional macrophage engineering programs, we plan to continue to selectively pursue collaborations with leading biopharmaceutical companies with particular experience, including development and commercial expertise and capabilities. We face significant competition in attracting appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we 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. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaboratorâ€™s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaboratorâ€™s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, the terms of any existing collaboration agreements, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate, document and execute. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration we may enter into may limit our ability to enter into future agreements on particular terms or covering similar target indications with other potential collaborators.If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate revenue from product sales, which could have an adverse effect on our business, prospects, financial condition and results of operations.We have a number of academic collaborations to supplement our internal discovery and product development programs. If any such collaborator decides to discontinue or devote less resources to such research, our discovery programs could be diminished.Our discovery engine is supplemented by academic collaborations to expand our platform, which we rely upon to advance our development and commercialization plans for our product candidates. For example, in August 2020, we entered into a scientific research and licensing agreement with Nathaniel R. Landau, Ph.D. and NYU Langone Health through which we obtained exclusive rights to develop their Vpx lentiviral vector globally for all indications. In addition, we, from time to time, may enter into academic research collaborations to explore the development of new technologies and indications.While these academic institutions have contractual obligations to us, they are independent entities and are not under our control or the control of our officers or directors. Our research and licensing agreements with academic collaborators generally provide academic collaborators with license maintenance fees, development and regulatory milestone payments, 52royalties on net sales of products and a portion of sublicense income that we receive. Upon the scheduled expiration of any academic collaboration, we may not be able to renew the related agreement, or any renewal could be on terms less favorable to us than those contained in the existing agreement. Furthermore, either we or the academic institution generally may terminate the sponsored research agreement for convenience following a specified notice period. If any of these academic institutions decides to not renew or to terminate the related agreement or decides to devote fewer resources to such activities, our discovery efforts would be diminished, while our royalty obligations, if any, would continue unmodified.Any acquisitions or in-license transactions that we complete could disrupt our business, cause dilution to our stockholders or reduce our financial resources.We have licensed three patent families from Penn and one patent family from NYU and may enter into transactions to in-license or acquire other businesses, intellectual property, technologies, product candidates or products. If we determine to pursue a particular transaction, we may not be able to complete the transaction on favorable terms, or at all. Any in-licenses or acquisitions we complete may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an in-license or acquisition or issue our common stock or other equity securities to the stockholders of the target company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. In-license and acquisition transactions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of additional future in-licenses or acquisitions or the effect that any such transactions might have on our operating results.The FDA, EMA, or other comparable foreign regulatory authorities could require the clearance or approval of a companion diagnostic device as a condition of approval for any product candidate that requires or would commercially benefit from such tests. Failure to successfully validate, develop and obtain regulatory clearance or approval for companion diagnostics on a timely basis or at all could harm our product development strategy and we may not realize the commercial potential of any such product candidate.If safe and effective use of any of our other product candidates depends on an in vitro diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates. The process of obtaining or creating such diagnostic is time consuming and costly. Companion diagnostics, which provide information that is essential for the safe and effective use of a corresponding therapeutic product, are subject to regulation by the FDA, EMA and other comparable foreign regulatory authorities as medical devices and require separate regulatory approval from therapeutic approval prior to commercialization. The FDA previously has required in vitro companion diagnostics intended to select the patients who will respond to a product candidate to obtain pre-market approval, or PMA, simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of pre-clinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous pre-market review during which the sponsor must prepare and provide the FDA with reasonable assurance of the deviceâ€™s safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record-keeping, and adverse event reporting.Given our limited experience in developing and commercializing diagnostics, we do not plan to develop companion diagnostics internally and thus will be dependent on the sustained cooperation and effort of third-party collaborators in developing and obtaining approval for these companion diagnostics. We may not be able to enter into arrangements with a provider to develop a companion diagnostic for use in connection with a registrational trial for our product candidates or for commercialization of our product candidates, or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates. We and our future collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by our collaborators to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. In addition, we, our collaborators or third parties may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics by physicians.53Any companion diagnostic collaborator or third party with whom we contract may decide not to commercialize or to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates, or our relationship with such collaborator or third party may otherwise terminate. We may not be able to enter into arrangements with another provider to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.Risks Related to Our Intellectual PropertyIf we are unable to obtain, maintain and enforce patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected and we may not be able to compete effectively in our market.Our commercial success depends in part on our ability to obtain, maintain and enforce protection of the intellectual property we may own solely and jointly with others or may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technologies and product candidates that are important to our business and by in-licensing intellectual property related to such technologies and product candidates. If we are unable to obtain, maintain or enforce patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Moreover, the patent applications we own, co-own or license may fail to result in issued patents in the United States or in other foreign countries.The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend or license 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. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business.The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the scope of patent protection outside of the United States is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. With respect to both owned and in-licensed

patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Moreover, our owned or in-licensed pending and future patent applications may not result in patents being issued which protect our technology and product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value or narrow the scope of our patent rights.Moreover, we or our licensors may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, inter 54partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.Our owned or licensed patent estate includes patent applications, many of which are at an early-stage of prosecution. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial costs and require significant time from our management and employees, even if the eventual outcome is favorable to us. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.Patent terms may be inadequate to protect our competitive position with respect to our current or future product candidates for an adequate amount of time.Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but there is no assurance that any such extensions will be obtained, and the life of a patent, and the protection it affords, is limited. Even if patents covering our current or future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.In the United States, patent term can also be adjusted due to delays that occur during examination of patent applications, which may extend the term of a patent beyond 20 years. There is a risk that we may take action that reduces any accrued patent term adjustment.It is necessary to pay certain maintenance fees, also referred to as annuities or renewal fees in some countries, throughout the lifetime of a patent at regular intervals. Failure to pay these fees can cause a granted patent to prematurely expire, without an opportunity for revival. There is a risk that we may be unable to maintain patent protection for certain patents in all markets due to finite availability of resources.If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidate(s), which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, we may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.55If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.Additionally, if we fail to comply with our obligations under any license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in us having to negotiate new or restated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.In the United States, the term of a patent that covers an FDA-approved drug may, in certain cases, be eligible for a patent term extension under the Hatch-Waxman Act, as compensation for the loss of a patent term during the FDA regulatory review process for a drug product subject to the provisions of the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years, but patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. There is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions could be for a shorter period than we anticipate. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.Changes in either the patent laws or interpretation of patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the maintenance, enforcement or defense of our owned or in-licensed issued patents.In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future.56The federal government retains certain rights in inventions created using its financial assistance under the Bayh-Dole Act. The federal government retains a â€œnonexclusive, nontransferable, irrevocable, paid-up licenseâ€ for its own benefit. The Bayh-Dole Act also provides federal agencies with â€œmarch-in rightsâ€. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a â€œnonexclusive, partially exclusive, or exclusive licenseâ€ to a â€œresponsible applicant or applicants.â€ If the patent owner refuses to do so, the government may grant the license itself. We collaborate with a number of universities with respect to certain of our research and development. We cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or in-license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.Although we or our licensors are not currently involved in any intellectual property litigation, we may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.Competitors and other third parties may infringe, misappropriate or otherwise violate our or our licensorâ€™s issued patents, the patents of our licensors or other intellectual property. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitorâ€™s product. To counter infringement or misappropriation, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming and can distract our management and scientific personnel. 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. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us, alleging that we infringe, misappropriate or otherwise violate their intellectual property.In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness, enablement, or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information

from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Similarly, if we or our licensors assert trademark infringement claims, a court may determine that the marks we or our licensors have asserted are invalid or unenforceable, or that the party against whom we or our licensors 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, which could materially harm our business and negatively affect our position in the marketplace.An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly, could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent, and could limit our or our licensorâ€™s ability to assert those patents against those parties, or other competitors, and curtail or preclude our ability to exclude third parties from developing and commercializing similar or competitive products. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. Even if we establish infringement, a court may not order the third party to stop using the technology at issue and instead award only monetary damages to us, which may not be an adequate remedy. 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 or trade secrets could be compromised by disclosure during this type of litigation. 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 material adverse effect on the price of our common stock. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects.Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our 57business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management, technical personnel and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.Any such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources in one or more aspects, or for other reasons. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or products, in which case we would be required to obtain a license from such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than us, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the biopharmaceutical industry. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as opposition proceedings before the European Patent Office. 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 pursuing development candidates. As the biopharmaceutical industry expands and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.The legal threshold for initiating litigation or contested proceedings is low, so even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. Even if we diligently search third-party patents for potential infringement by our products or product candidates, we may not successfully find patents our products or product candidates may infringe. We may not be aware of all such intellectual property rights potentially relating to our technology 58and product candidates and their uses, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third partyâ€™s intellectual property.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 materials, formulations or methods, such as methods of manufacture or methods for treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial 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.We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third partyâ€™s intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, we could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for significant monetary damages, including treble damages and attorneysâ€™ fees, if we are found to have willfully infringed a patent or other intellectual property right, we could be forced to indemnify our customers or collaborators. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.While we seek to protect the trademarks and trade names we use in the United States and in other countries, we may be unsuccessful in obtaining registrations or otherwise protecting these trademarks and trade names, which we need to build name recognition in our markets of interest and among potential partners or customers. We rely on both registration and common law protection for our trademarks. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted or declared generic, or determined to be infringing on other marks. At times, competitors may adopt trademarks and trade names similar to ours, or our collaborators may fail to use our trade names or trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. If we are unable to protect our rights to trademarks and trade names, we may be prevented from using such marks and names unless we enter into appropriate royalty, license or coexistence agreements, which may not be available or may not be available on commercially reasonable terms.During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and 59to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.We may license our trademarks and trade names to third parties, such as distributors and collaborators. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of or failure to use our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our

proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business, financial condition, results of operations and prospects.60If we fail to comply with our obligations in our current and future intellectual property licenses and funding arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.We are party to a number of license and research agreements. Some of these agreements provide us with the intellectual property rights required for the development of our product candidates, including the license agreement with Penn. These licenses and research agreements and similar agreements in the future may impose diligence, development and commercialization timelines, and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with such obligations, the parties to these agreements may decide to terminate the agreements or require us to grant them certain rights, in which we may not be able to develop, manufacture, or market any products without the rights granted to us by these agreements and may face other penalties. Any such occurrences could adversely affect the value of any product candidate being developed, including CT-0525.For a variety of purposes, we will likely enter into additional licensing and funding arrangements with third parties that may impose similar obligations on us. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or restated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. While we still face all of the risks described herein with respect to such agreements, we cannot prevent third parties from also accessing those technologies. In addition, our licenses may place restrictions on our future business opportunities.In addition to the above risks, intellectual property rights that our licenses in the future may include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.Disputes may arise regarding intellectual property subject to a licensing agreement, including:â€¢the scope of rights granted under the license agreement and other interpretation related issues;â€¢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 patent and other rights under our collaborative development relationships;â€¢our diligence obligations under the license agreement and what activities satisfy those diligence obligations;â€¢the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; andâ€¢the payment obligations with respect to licensed technology.In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.Further, licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on our licensors to control the prosecution, maintenance and enforcement of all of our licensed and sublicensed intellectual property, and even when we do have such rights, we may require the cooperation of our licensors and upstream licensors, which may not be forthcoming. Licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Our business could be adversely affected if we or our licensors are unable to prosecute, maintain and enforce our licensed and sublicensed intellectual property effectively.Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications of our in-licenses. If 61other third parties have ownership rights to patents or patent applications of our in-licenses, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.We may not be able to protect our intellectual property and proprietary rights throughout the world.Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. 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, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and 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, further, may export otherwise infringing products to territories where we have patent protection or licenses, but enforcement 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, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment.Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions 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, held unenforceable or interpreted narrowly, could put our patent applications at risk of not issuing, 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. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our 62or our licensorsâ€™ ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, including of their current or former employers or claims asserting we have misappropriated their intellectual property, or is claiming

ownership of what we regard as our own intellectual property.Many of our employees, consultants and contractors have been previously employed at universities or other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individualâ€™s current or former employer. Litigation may be necessary to defend against these claims.If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We may have also entered into confidentiality and invention or patent assignment agreements with our employees and consultants, but we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. To the extent we become involved in litigation that may require discovery of our trade secrets, know-how and other proprietary technology, we will seek to secure protective orders from the court that bind the parties with access to the discovered information. Despite these efforts, 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. Detecting the disclosure or misappropriation of a trade secret and 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 of the United States are less willing or unwilling to protect trade secrets. In addition, we cannot be certain that proprietary technical information and related confidential documents that we have shared with our collaborators and/or submitted to governmental agencies, including regulatory agencies for evaluation and supervision of pharmaceutical products, will be kept confidential. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.63Intellectual property rights do not necessarily address all potential threats to us.The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:â€¢others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or license;â€¢we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;â€¢we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering our inventions;â€¢others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;â€¢it is possible that our owned or in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;â€¢claims of issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;â€¢our competitors might conduct research, development, testing or commercialization activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;â€¢we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;â€¢we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;â€¢the U.S. Supreme Court, other federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our or our licensorsâ€™ patents;â€¢patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;â€¢we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;â€¢we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;â€¢we may not develop additional proprietary technologies that are patentable;â€¢the patents of others may harm our business; andâ€¢we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.If approved, our product candidates that are licensed and regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as â€œinterchangeableâ€ based on its similarity to an approved biologic. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product In addition, the licensure 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 develop and receive approval of a competing biologic, so long as its biologics license application, or BLA, does not reply on the reference product, sponsorâ€™s data or submit the application as a biosimilar application. 64We believe that any of the product candidates we develop as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. Nonetheless, the approval of a biosimilar to our product candidates would have a material adverse impact on our business due to increased competition and pricing pressure.Risks Related to Regulatory Approval and Other Legal Compliance MattersThe regulatory approval process of the FDA is lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidateâ€™s clinical development and may vary among jurisdictions. We have not obtained marketing approval for any product candidate, and it is possible that none of our existing product candidates, or any product candidates we may seek to develop in the future will ever obtain marketing approval.Our product candidates could fail to receive marketing approval for many reasons, including the following:â€¢the FDA may disagree with the design or implementation of our clinical trials;â€¢we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for our proposed indication;â€¢results of clinical trials may not meet the level of statistical significance required by the FDA for approval;â€¢we may be unable to demonstrate that a product candidateâ€™s clinical and other benefits outweigh its safety risks;â€¢the FDA may disagree with our interpretation of data from pre-clinical studies or clinical trials;â€¢data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application, or NDA, to the FDA or other submission or to obtain marketing approval in the United States;â€¢the FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; andâ€¢the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.This lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain marketing approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. The FDA has substantial discretion in the approval process and determining when or whether marketing approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA. Risks similar to those outlined above exist with regard to regulatory authorities outside the United States.In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.Even if we complete the necessary pre-clinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import are subject to comprehensive regulation by the FDA and other regulatory authorities in the 65United States and by the EMA and other regulatory authorities outside of the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction.We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive pre-clinical and clinical data and supporting information, including manufacturing information, to the various regulatory authorities for each therapeutic indication to establish the product candidateâ€™s safety and efficacy. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed.The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may

decide that our data is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.Further, under the Pediatric Research Equity Act of 2003, or PREA, a BLA or supplement to a BLA for certain biological products must contain data to assess the safety and effectiveness of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In Loper Bright Enterprises v. Raimondo, for example, the court overruled Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act, or the APA. Additionally, in Corner Post, Inc. v. Board of Governors of the Federal Reserve System, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.Finally, our ability to develop and market new drug products may be impacted if litigation challenging the FDAâ€™s approval of another companyâ€™s drug continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, if it continues, our 66ability to develop new drug product candidates and to maintain approval of existing drug products is at risk and could be delayed, undermined or subject to protracted litigation.Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.In order to market and sell our products in the European Union and many other foreign jurisdictions, we and our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any jurisdiction, which would materially impair our ability to generate revenue.Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and EU Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, became responsible for supervising medicines and medical devices in Great Britain, or GB, comprising England, Scotland and Wales under domestic law, whereas under the terms of the Northern Ireland Protocol, Northern Ireland is currently subject to EU rules. The United Kingdom and European Union have however agreed to the Windsor Framework which fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. From January 1, 2025, the changes introduced by the Windsor Framework will see the MHRA be responsible for approving all medicinal products destined for the United Kingdom market (i.e., GB and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. Any delay in obtaining, or an inability to obtain, any marketing authorizations, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commissionâ€™s proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. On April 10, 2024, the European Parliament adopted a position on the proposal requesting several amendments to the package. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agenciesâ€™ operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, 67regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. In addition, disruptions may result from events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDAâ€™s inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.Accordingly, if a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.Regulatory requirements governing gene therapy products are periodically updated and may continue to change in the future.The FDA has established the Office of Tissues and Advanced Therapies, or the OTAT, within the Center for Biologics Evaluation and Research, or the CBER, to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review. In September 2022, the FDA announced retitling of the OTAT to the Office of Therapeutic Products, or the OTP, and elevation of the OTP to a â€œSuper Officeâ€ to meet its growing cell and gene therapy workload and new commitments under the Prescription Drug User Fee Act agreement for fiscal years 2023 to 2027. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the NIH also are potentially subject to review by the Office of Biotechnology Activitiesâ€™ Recombinant DNA Advisory Committee, or the RDAC; however, the NIH announced that the RDAC will only publicly review clinical trials if the trials cannot be evaluated by standard oversight bodies and pose unusual risks. Although the FDA decides whether individual gene therapy protocols may proceed, the RDAC public review process, if undertaken, can delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Conversely, the FDA can put an IND on a clinical hold even if the RDAC has provided a favorable review or an exemption from in-depth, public review. If we were to engage an NIH-funded institution to conduct a clinical trial, that institutionâ€™s Institutional Biosafety Committee, or IBC, as well as our IRB would need to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of our product candidates.The FDA has issued various guidance documents regarding gene therapies, including final guidance documents released in January 2020 relating to CMC information for gene therapy INDs, gene therapies for rare diseases and gene therapies for retinal disorders. Although the FDA has indicated that these and other guidance documents it previously issued are not legally binding, we believe that our compliance with them is likely necessary to gain approval for any gene therapy product candidate that we may develop. The guidance documents provide additional factors that the FDA will consider at each of the above stages of development and relate to, among other things, the proper pre-clinical assessment of gene therapies; the chemistry, manufacturing, and control information that should be included in an IND; the proper design of tests to measure product potency in support of an IND or BLA; and measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies when the risk of such effects is high. Further, the FDA usually recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by 10 years of annual queries, either in person or by questionnaire.68Further, for a gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with good tissue practices, or GTP. These standards are

found in FDA regulations and guidance that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission, and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.Finally, ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations or prohibiting the processes that we may use. Federal and state agencies, congressional committees and foreign governments have expressed their intentions to further regulate biotechnology. More restrictive regulations or claims that our product candidates are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.As we advance our product candidates through clinical development, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue.Any product for which we obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with any such product following approval.Any product for which we obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS.The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturersâ€™ communications regarding off-label use and if we market any product for an indication that is not approved, we may be subject to warnings or enforcement action for off-label marketing. Violation of the Federal Food, Drug, and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.In addition, later discovery of previously unknown adverse events or other problems with any product for which we may obtain marketing approval and its manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:â–ªrestrictions on such product, manufacturers or manufacturing processes;â–ªrestrictions on the labeling or marketing of the product;â–ªrestrictions on product distribution or use;â–ªrequirements to conduct post-marketing studies or clinical trials;â–ªwarning letters or untitled letters;â–ªwithdrawal of the product from the market;69â–ªrefusal to approve pending applications or supplements to approved applications that we submit;â–ªrecall of the product;â–ªrestrictions on coverage by third-party payors;â–ªfines, restitution or disgorgement of profits or revenues;â–ªsuspension or withdrawal of marketing approvals;â–ªrefusal to permit the import or export of the product;â–ªproduct seizure; orâ–ªinjunctions or the imposition of civil or criminal penalties.Similar restrictions apply to the approval of our products in the EU. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the EUâ€™s stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturerâ€™s license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the European Union and are also subject to EU Member State laws. The failure to comply with these and other EU requirements can also lead to significant penalties and sanctions.Any regulatory approval to market our products will be limited by indication. If we fail to comply or are found to be in violation of FDA regulations restricting the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, EMA, MHRA and other government agencies. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. Physicians may nevertheless prescribe our products off-label to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in October 2023, the FDA published draft guidance outlining the agencyâ€™s non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. In addition, under some relatively recent guidance from the FDA and the PIE Act, signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDAâ€™s various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products. In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneysâ€™ Offices, the Office of Inspector General of the HHS, the FDA, the Federal Trade Commission, or the FTC, and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as â€œqui tamâ€ actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as â€œwhistleblower suits,â€ are often brought by current or former employees. In a qui 70tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the United States, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track productâ€™s application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. In June 2024, the FDA granted Fast Track designation for CT-0525 for the treatment of solid tumors that overexpress HER2.We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.We may seek PRIME Designation in the European Union for our product candidates, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.In the EU, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMAâ€™s role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and where the sponsor intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest

and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a rapporteur under the EMA's Committee for Human Medicinal Products to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning 71reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables a sponsor to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMAâ€™s grant of a marketing authorization.We, or our collaborators, may seek approval from the FDA or comparable foreign regulatory authorities to use accelerated development pathways for our product candidates. If we, or our collaborators, are not able to use such pathways, we, or they, may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay the receipt of, necessary marketing approvals, if we, or they, receive them at all. In addition, even if an accelerated approval pathway is available to us, or our collaborators, it may not lead to expedited approval of our product candidates, or approval at all.Under the FDCA and implementing regulations, the FDA may grant accelerated approval to a product candidate to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. Prior to seeking such accelerated approval, we, or our collaborators, will continue to seek feedback from the FDA or comparable foreign regulatory agencies and otherwise evaluate our, or their, ability to seek and receive such accelerated approval.There can be no assurance that we will satisfy all FDA requirements, including new provisions that govern accelerated approval. For example, with passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months (until the study is completed; and use expedited procedures to withdraw accelerated approval of an NDA or BLA if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to â€œconditions specified by the Secretary.â€ The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner or the Commissionerâ€™s designee and a written appeal, among other things. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval.In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. While this guidance is currently only in draft form and will not be legally binding even when finalized, we will need to consider the FDAâ€™s guidance closely if we seek accelerated approval for any of our products.In the European Union, a â€œconditionalâ€ marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a â€œstandardâ€ marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.72There can be no assurance that the FDA or comparable foreign regulatory agencies will agree with our, or our collaboratorsâ€™, surrogate endpoints or intermediate clinical endpoints in any of our, or their, clinical trials, or that we, or our collaborators, will decide to pursue or submit any additional application for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we, or our collaborators, will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval. Furthermore, for any submission of an application for accelerated approval or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period until commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.We may not be able to obtain orphan drug exclusivity for any product candidates we may develop, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.In order for the FDA to grant orphan drug exclusivity to one of our products, the FDA must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA and comparable foreign regulatory authorities such as the EMA can subsequently approve the same product for the same condition if the FDA or such other authorities conclude that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.In 2017, the Congress passed the FDA Reauthorization Act, or FDARA. The FDARA, among other things, codified the FDAâ€™s pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. Under omnibus legislation signed by former President Trump in December 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of the FDARA in 2017, but have not yet been approved or licensed by the FDA.The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term â€œsame disease or conditionâ€ means the designated â€œrare disease or conditionâ€ and could not be interpreted by the FDA to mean the â€œindication or use.â€ Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the â€œindication or use.â€ Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. 73We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.If we are required by the FDA, EMA or comparable regulatory authority to obtain clearance or approval of a companion diagnostic test in connection with approval of any of our product candidates or a group of therapeutic products, and we do not obtain or we face delays in obtaining clearance or approval of a diagnostic test, we may not be able to commercialize the product candidate and our ability to generate revenue may be materially impaired.If we are required by the FDA, EMA or a comparable regulatory authority to obtain clearance or approval of a companion diagnostic test in connection with approval of any of our product candidates, such companion diagnostic test would be used during our more advanced phase clinical trials as well as in connection with the commercialization of our product candidates. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to ensuring the safe and effective use of a novel therapeutic product or new indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared. In certain circumstances (for example, when a therapeutic product is intended to treat a serious or life-threatening condition for which no satisfactory available therapy exists or when the labelling of an approved product needs to be revised to address a serious safety issue), however, the FDA may approve a therapeutic product without the prior or contemporaneous marketing authorization of a companion diagnostic. In this case, approval of a companion diagnostic may be a post-marketing requirement or commitment.Co-development of companion diagnostics and therapeutic products is critical to the advancement of precision medicine. Whether initiated at the outset of development or at a later point, co-development should generally be conducted in a way that will facilitate obtaining contemporaneous marketing authorizations for the therapeutic product and the associated companion diagnostic. If a companion diagnostic is required to identify patients who are most likely to benefit from receiving the product, to be at increased risk for serious adverse events as a result of treatment with a particular therapeutic product, or to monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness, then the FDA has required marketing approval of all companion diagnostic tests essential for the safe and effective use of a therapeutic product for cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any future diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization in those countries.The approval of a companion diagnostic as part of the therapeutic productâ€™s labeling limits the use of the therapeutic product to only those patients who express the specific genomic alteration or mutation alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires clearance or approval of a companion diagnostic for any of our product candidates, whether before, concurrently with approval, or

post-approval of the product candidate, we, and/or future collaborators, may encounter difficulties in developing and obtaining clearance or approval for these companion diagnostics. The process of obtaining or creating such companion diagnostics is time consuming and costly. The FDA previously has required in vitro companion diagnostics intended to select the patients who will respond to a product candidate to obtain PMA, simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of pre-clinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous pre-market review during which the sponsor must prepare and provide FDA with reasonable assurance of the deviceâ€™s safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record-keeping, and adverse event reporting.Any delay or failure by us or third-party collaborators to develop or obtain regulatory clearance or approval of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. This guidance and future issuances from the FDA, EMA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and could result in delays in regulatory clearance or approval or a change in the determination for whether or not a companion diagnostic is still required for our product candidates. We may be 74required to conduct additional studies to support a broader claim or more narrowed claim for a subset population. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include any of our future approved product candidates covered indications, we may no longer need to continue our companion diagnostic development plans or we may need to alter those companion diagnostic development strategies, which could adversely impact our ability to generate revenue from the sale of our companion diagnostic test.Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining clearance or approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory clearance or approval processes. Moreover, even if data from pre-clinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory clearance or approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance.If we are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the co-development or commercialization of our companion diagnostic and therapeutic product candidates.Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to civil, criminal and administrative sanctions, contractual damages, reputational harm and diminished future profits and earnings.Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any drugs for which we obtain marketing approval. Our future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable state and federal fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. These include the following:â€¢Anti-Kickback Statute - prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, ordering, leasing, arranging for, or recommending the purchasing, ordering, or leasing of, any good or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare or Medicaid;â€¢False Claims Act - the federal civil and criminal false claims laws, including the civil False Claims Act, and Civil Monetary Penalties Law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, false or fraudulent claims for payment or knowingly making, using or causing to made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government;â€¢Health Insurance Portability and Accountability Act, or HIPAA - the federal HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and apply regardless of the payor (e.g., public or private);â€¢HIPAA and HITECH - HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which impose obligations on HIPAA covered entities and their business associates, including mandatory contractual terms and required implementation of 75administrative, physical and technical safeguards to maintain the privacy and security of individually identifiable health information;â€¢Transparency Requirements - the federal physician transparency requirements known as the Physician Payments Sunshine Act, under the ACA, as amended by the Health Care Education Reconciliation Act, which requires manufacturers of drugs, medical devices, biological and medical supplies covered by Medicare, Medicaid, or State Childrenâ€™s Health Insurance Program to report annually to the CMS, within the HHS information related to payments and other transfers of value made by that entity to physicians, other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; andâ€¢Analogous State, Local and Foreign Laws - analogous state, local and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader than similar federal laws, can apply to claims involving healthcare items or services regardless of payor, and are enforced by many different federal and state agencies as well as through private actions.Some state laws require pharmaceutical companies to comply with the pharmaceutical industryâ€™s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, as well as tracking and reporting of transfers of value by pharmaceutical manufacturers to physicians and healthcare organizations, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and/or administrative penalties, damages, fines, individual imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations 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. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States.Current and future legislation may increase the difficulty and cost for us and any of our collaborators to obtain marketing approval of and commercialize product candidates and affect the prices we, or any of our collaborators, may obtain.In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, impact pricing and reimbursement and affect our ability, or the ability of any of our collaborators, to profitably sell or commercialize any product candidates for which we, or any of our collaborators, obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any of our collaborators, may receive for any FDA approved products.In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for prescription drugs purchased through a pharmacy by the elderly and disabled and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this statute provides authority for 76limiting the number of drugs that will be covered in any therapeutic class, subject to certain exceptions. Cost reduction initiatives and other provisions of this statute could decrease the coverage and price that we receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.In March 2010, then-President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislationâ€™s automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the CARES Act. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Under current legislation, the actual reductions in Medicare payments may vary up to 4%.The Consolidated Appropriations Act, or the Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Appropriation Actâ€™s health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the

payment reduction percentages in fiscal years 2030 and 2031.Further, with passage of the Inflation Reduction Act, or the IRA, Congress extended the expansion of the Patient Protection and Affordable Care Act premium tax credits through 2025. Those subsidies were originally extended through 2022 under the American Rescue Plan Act of 2021. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.Since enactment of the ACA, there have been and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, Congress repealed the â€œindividual mandate.â€ The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, in June 2021, the U.S. Supreme Court dismissed a lawsuit challenging the constitutionality of the ACA after finding that the plaintiffs do not have standing to bring the litigation. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.The Trump administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden rescinded those orders and issued a new executive order which directs federal agencies to reconsider rules and other policies that limit Americansâ€™ access to health care and consider actions that will protect and strengthen that access. Under this order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the health insurance marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. This executive order also directs the HHS to create a special enrollment period for the health insurance marketplace in response to the COVID-19 pandemic.In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once 77applicable, it will have a phased implementation depending on the products concerned. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies 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 technology, and making decisions on pricing and reimbursement.We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to scrutiny and considerable legislative and executive actions that could impact the prices we obtain for our drug products, if and when approved.The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States and foreign jurisdictions. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, former President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, the CMS issued a final rule to rescind it. With issuance of this rule, the CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiariesâ€™ access to evidence-based care.In addition, in October 2020, the HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue the HHS. Seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont) have passed laws allowing for the importation of drugs from Canada. North Dakota and Virginiaâ€¯have passed legislation establishing workgroups to examine the impact of a state importation program.â€¯As of May 2024, five states (Colorado, Florida, Maine, New Hampshire and New Mexico) had submitted Section 804 Importation Program proposals to the FDA and, on January 5, 2024, the FDA approved Floridaâ€™s plan for Canadian drug importation. That state now has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. The state will also need to relabel the drugs and perform quality testing of the products to meet FDA standards. Further, on November 20, 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed, and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. The IRA further delayed implementation of this rule to January 1, 2032. 78On August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years. The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023 and the second cycle will commence in the Fall 2024.Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated â€œmaximum fair priceâ€ under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at 2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or â€œcatastrophic periodâ€ of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRAâ€™s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, or the Chamber, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.At the state level, individual states are increasingly aggressive in passing legislation and implementing 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. In addition, health care organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.79In other countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we, or our collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our drug to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing

our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.Our operations are subject to anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA, the Bribery Act, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act, and these other laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act, or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, United Kingdom, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, which is collectively referred to as Trade Control Laws.There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act, or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act, and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have a material adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPAâ€™s accounting provisions. Likewise, any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control Laws by the United States, the United Kingdom or other authorities could also have an adverse impact on our reputation, business, results of operations and financial condition.We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, the European Union and the United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in an enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can 80be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. The HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.In addition to potential enforcement by the HHS, we are also potentially subject to privacy enforcement from the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be â€œunfairâ€ under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTCâ€™s evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the CCPA which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPAâ€™s requirements are similar to those found in the General Data Protection Regulation, or the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of â€œsalesâ€ of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the CPRA, which will significantly expand the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. Most CPRA provisions took effect on January 1, 2023, though the obligations apply to any personal information collected after January 1, 2022. These provisions may apply to some of our business activities. In addition to California, at least 18 other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of â€œsensitiveâ€ data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2024 legislative sessions that will go into effect in 2025 and beyond. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation in 2024. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on 81companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partnersâ€™ or service providersâ€™ privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20.0 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the EU, or the CJEU, invalidated the European Union-United States Privacy Shield, or Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. While we are not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States, generally, and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.Following the CJEU decision, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the European Commission adopted the adequacy decision in July 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business.On June 23, 2016, the electorate in the United Kingdom. voted in favor of leaving the European Union, commonly referred to as Brexit. As with other issues related to Brexit, there are open questions about how personal data will be protected in the United Kingdom. and whether personal information can transfer from the European Union to the United Kingdom. Following the withdrawal of the United Kingdom from the European Union, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. While the Data Protection Act of 2018 in the United Kingdom that â€œimplementsâ€ and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under the GDPR, although these transfers currently are permitted by an adequacy decision from the European Commission. The United Kingdom government has already determined that it considers all European Union 27 and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom. to the EU/EEA remain unaffected. In addition, a recent decision from the European Commission appears to deem the United Kingdom. as being â€œessentially adequateâ€ for purposes of data transfer from the European Union to the United Kingdom., although this decision may be re-evaluated in the future. The United Kingdom. and the United States. have also agreed to a U.S.-UK â€œData Bridge,â€ which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the United Kingdom to the United States. In addition to the United Kingdom., Switzerland is also in the process of approving an

adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-UK Data Bridge in relation to data transfers from Switzerland to the United States). Any changes or updates to these developments have the potential to impact our business.Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and any eventual sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions.While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant 82resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.If our employees, independent contractors, consultants, collaborators and vendors engage in misconduct or other improper activities, including non-compliance with regulatory standards and/or requirements and insider trading, we could sustain significant liability and harm to our reputation.We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, collaborators and vendors. Misconduct by these partners could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state laws, and requirements of foreign jurisdictions, including the GDPR. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter employee or third-party misconduct, and the precautions that we take to detect and prevent these activities 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, standards, regulations, guidance or codes of conduct. 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 and results of operations, including the imposition of significant fines or other sanctions.If we or any third-party manufacturer we engage now or in the future fails to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could significantly harm our business.We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Although we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.We maintain general liability insurance as well as workersâ€™ compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.83Risks Related to Employee Matters and Managing GrowthOur reduction in force undertaken to extend our cash runway and focus more of our capital resources on our prioritized research and development programs might not achieve our intended outcome.In late March 2024, our board of directors approved a reduction in force affecting approximately 37% of our total workforce, in order to preserve cash and prioritize investment in our core clinical programs. The reduction in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while positions have been eliminated, certain functions necessary to our operations remain, and we might not successfully distribute the duties and obligations of our terminated employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the reduction in force, or if we experience significant adverse consequences from the reduction in force, our business, financial condition and results of operations may be materially adversely affected.Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain and motivate qualified personnel.We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we entered into employment agreements with certain of our executive officers, each of them may terminate their employment with us at any time. We do not maintain â€œkey personâ€ insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel is also critical to our success.The loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our discovery programs, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous biopharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Failure to succeed in clinical trials may make it even more challenging to recruit and retain qualified scientific personnel. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.We expect to experience significant growth in the number of our employees and the scope of our operations, particularly as we function as a public company and in the areas of product development, clinical, regulatory affairs, manufacturing and quality control and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Future growth will impose significant added responsibilities on members of our management, including:â€¢identifying, recruiting, integrating, maintaining and motivating additional employees;â€¢managing our internal development efforts effectively, including the clinical and regulatory review process for CT-0525 and other product candidates we are developing or may develop in the future, while complying with our contractual obligations to contractors and other third parties; andâ€¢improving our operational, financial and management controls, reporting systems and procedures.84Our future financial performance and our ability to advance development of and, if approved, commercialize CT-0525 and any other product candidate we are developing or may develop in the future will depend, in part, on our ability to effectively manage any future growth. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations could also lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.Many of the biopharmaceutical companies, and in particular cell therapy companies, that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can develop product candidates and operate our business will be limited.Our internal computer systems, or those of our collaborators, vendors, suppliers, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.Our internal computer systems and those of any of our collaborators, vendors, suppliers, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or email fraud to cause payments or information to be transmitted to an unintended recipient.If we experience any material system failure, accident, cyber-attack or security that causes interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development

and commercialization of our product candidates could be delayed.Our employees, independent contractors, including principal investigators, consultants and vendors and any third parties we may engage in connection with discovery programs, research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could cause significant liability for us and harm our reputation.We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, including principal investigators, consultants and vendors and any other third parties we engage. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that include failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide complete and accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state data privacy, security, fraud and other healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report complete financial information or data accurately or disclose unauthorized activities to us. Misconduct by employees and other third parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the EU Data Protection Directive. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in 85controlling 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, standards, regulations, guidance or codes of conduct. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.Risks Related to the Ownership of Our Common StockThe market price of our common stock may be volatile, and the market price of our common stock may drop in the future.The market price of our common stock could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:â€¢results of clinical trials and pre-clinical studies of our product candidates, or those of our competitors or our existing or future collaborators;â€¢failure to meet or exceed financial and development projections we may provide to the public;â€¢failure to meet or exceed the financial and development projections of the investment community;â€¢announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;â€¢actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;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 qualified scientific and management personnel;â€¢significant lawsuits, including patent or stockholder litigation;â€¢if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;â€¢changes in the market valuations of similar companies;â€¢general market or macroeconomic conditions or market conditions in the biopharmaceutical sector;â€¢sales of securities by us or our stockholders in the future;â€¢if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates;â€¢trading volume of our common stock;â€¢announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;â€¢adverse publicity relating to product candidates, including with respect to other products in such markets;â€¢the introduction of technological innovations or new therapies that compete with our products and services; andâ€¢period-to-period fluctuations in our financial results.Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a companyâ€™s securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased stockholder activism if we experience a market valuation that activists believe is not reflective of its intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.86We incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.We incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Some of our management team has not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directorsâ€™ and officersâ€™ insurance, on acceptable terms..We do not currently meet the requirements for continued listing on the Nasdaq Global Market. If we fail to meet the requirements for continued listing on the Nasdaq Global Market, our common stock could be delisted from trading, which would have a negative effect on the price of our common stock and our ability to raise additional capital.Our common stock is currently listed on The Nasdaq Global Market. We are required to meet specified requirements to maintain our listing on The Nasdaq Global Market, including, among other things, a minimum market value of listed securities of $50,000,000 under Nasdaq Listing Rule 5450(b)(2)(A), or the Minimum MVLS Requirement.On October 10, 2024, we received written notice, or the Notice, from the Listing Qualifications Department, or the Staff, of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that our common stock was not in compliance with the Minimum MVLS Requirements for the previous 30 consecutive business days required to maintain continued listing on The Nasdaq Global Market. The Notice has no immediate effect on the listing of our common stock. We have 180 calendar days, or until April 8, 2025, to regain compliance with the Minimum MVLS Requirement. If, at any time before April 8, 2025, the market value of our listed securities closes at $50.0 million or more for a minimum of ten consecutive business days, the Staff will provide written notification to us that we have regained compliance with the Minimum MVLS Requirement and this matter will be closed. If we do not regain compliance with the Minimum MVLS Requirement by April 8, 2025, we will receive written notification that our securities are subject to delisting. At that time, we may appeal the Staffâ€™s delisting determination to a Nasdaq Listing Qualifications Panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules.If we fail to satisfy The Nasdaq Global Marketâ€™s continued listing requirements, we may transfer to The Nasdaq Capital Market, which generally has lower financial requirements for initial listing, to avoid delisting, or, if we fail to meet its listing requirements, the OTC Bulletin Board. However, we may not be able to satisfy the initial listing requirements for The Nasdaq Capital Market. A transfer of our listing to The Nasdaq Capital Market or having our common stock trade on the OTC Bulletin Board could adversely affect the liquidity of our common stock. Any such event could make it more difficult to dispose of, or obtain accurate quotations for the price of, our common stock, and there also would likely be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. We may also face other material adverse consequences in such event, such as negative publicity, a decreased ability to obtain additional financing, diminished investor and/or employee confidence, and the loss of business development opportunities, some or all of which may contribute to a further decline in our stock price.A delisting of our common stock from The Nasdaq Global Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all and would also make it more difficult for our stockholders to sell or purchase our common stock when they wish to do so. In the event of a delisting, we would take actions to restore our compliance with the Nasdaq Global Marketâ€™s listing requirements, but we can provide no assurance that any action taken by us would result in our common stock becoming listed again, or that any such action would stabilize the market price or improve the liquidity of our common stock.If a significant portion of our total outstanding shares are sold into the market, the market price of our common stock could drop significantly, even if our business is doing well. 87Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Certain of our stockholders have rights, subject to specified conditions, under our resale registration statement on Form S-3 registering 3,730,608 shares of our common stock under which they may sell their shares of common stock in the public market, so long as the resale registration statement on Form S-3 remains effective. We have also filed a registration statement registering all shares of common stock that we may issue under our equity compensation plans. Moreover, we are also party to the Sale Agreement with Jefferies, as sales agent, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time through Jefferies under an â€œat-the-market offeringâ€ program, or ATM. The number of shares that are sold by Jefferies after we request that sales be made will fluctuate based on the market price of our common stock during the sales period and limits we set with Jefferies. Therefore, it is not possible to predict the number of shares that will ultimately be issued by us, if any, pursuant to the sales agreement. As of SeptemberÂ 30, 2024, we have sold 1,362,917 shares under the ATM for gross proceeds of $3.2 million.If at some point we are no longer a â€œsmaller reporting companyâ€ or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.We will be subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as a â€œsmaller reporting company,â€ as defined in Item 10(f)(1) of Regulation S-K, we may take advantage of certain exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2022 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. If at some point we are no longer qualified as a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, then we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.Our executive officers, directors and principal stockholders may have the ability to significantly influence all matters submitted to our stockholders for approval.As of SeptemberÂ 30, 2024, our executive officers, directors and principal stockholders, in the aggregate, beneficially owned 46.4% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or

prevent an acquisition of the Company on terms that other stockholders may desire.We have broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we may not be able to yield a significant return, if any, on our investment of these net proceeds. You do not have the opportunity to influence our decisions on how to use our cash resources.88Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.Recent Sales of Unregistered SecuritiesDuring the period covered by this Quarterly Report on Form 10-Q, we did not issue any unregistered equity securities other than pursuant to transactions previously disclosed in our Current Reports on Form 8-K.Purchase of Equity SecuritiesWe did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.Item 5. Other Information.As previously disclosed, on September 20, 2022, the Company and Legacy Carisma entered into an Agreement and Plan of Merger and Reorganization, as amended by the First Amendment thereto dated as of December 29, 2022 and the Second Amendment thereto dated as of February 13, 2023, by and among the Company, Legacy Carisma and Merger Sub, pursuant to which, among other matters, Merger Sub merged with and into Legacy Carisma, with Legacy Carisma continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger, or the Merger. On December 21, 2022, a putative class action complaint was filed in the Court of Chancery of the State of Delaware, or the Court, by Sholom Keller, a stockholder of the Company, against the Company and the then-members of our board of directors, captioned Keller v. Sesen Bio, Inc. et al., C.A. No. 2022-1186-KSJM, or the Action. The complaint alleged that the disclosures made in Amendment No. 2 to our Registration Statement on Form S-4 filed with the SEC on December 14, 2022, in connection with the Merger, contained false and misleading statements. The complaint sought, among other forms of relief, a preliminary injunction to enjoin the Merger. The plaintiff and defendants agreed on certain additional disclosures, which we made in Amendment No. 3 to our Registration Statement on Form S-4 filed with the SEC on January 9, 2023, or the January 9 Amendment, and the supplement to our proxy statement/prospectus dated January 19, 2023 and filed with the SEC on February 16, 2023, or the Proxy Statement/Prospectus Supplement. On February 21, 2023, the plaintiff voluntarily dismissed the Action as moot, and on March 13, 2023, the Court entered a stipulated order dismissing the Action with prejudice as to the plaintiff and without prejudice as to the putative class members. The Court retained jurisdiction solely for the purpose of adjudicating plaintiffâ€™s counselâ€™s anticipated application for an award of attorneysâ€™ fees and reimbursement of expenses in connection with the disclosures in the January 9 Amendment and the Proxy Statement/Prospectus Supplement. In order to avoid the time and expense of continued litigation, we, as successor in interest of Sesen Bio, Inc., subsequently agreed to pay $80,000 to plaintiffâ€™s counsel for attorneysâ€™ fees and expenses in full satisfaction of their claim for attorneysâ€™ fees and expenses in the Action. On August 7, 2023, the Court entered an order closing the case, subject to us filing an affidavit with the Court confirming that this notice has been issued. In entering the order, the Court was not asked to review, and did not pass judgment on, the payment of the attorneysâ€™ fees and expenses or their reasonableness.Director and Officer Trading ArrangementsNone of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as such terms are defined in Items 408(a) and 408(c) of Regulation S-K, respectively) during the quarterly period covered by this report.89Item 6. Exhibits.ExhibitNumberÂ Description3.1Restated Certificate of Incorporation of Carisma Therapeutics Inc., dated March 7, 2023 (incorporated by reference to Exhibit 3.1 to the registrantâ€™s Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).3.2Amended and Restated By-Laws of Carisma Therapeutics Inc., dated March 7, 2023 (incorporated by reference to Exhibit 3.2 to the registrantâ€™s Current Report on Form 8-K (File No. 001-36296) filed on March 8, 2023).3.3Certificate of Amendment of Carisma Therapeutics Inc., dated June 6, 2023 (incorporated by reference to Exhibit 3.1 to the registrantâ€™s Current Report on Form 8-K (File No. 001-36296) filed on June 9, 2023).31.1*Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 200231.2*Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 200232.1+Certifications of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 200232.2+Certifications of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002101The following financial information from Carisma Therapeutics Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 formatted in Inline XBRL (Extensible Business Reporting Language) includes: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Comprehensive Loss, (iii) the Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit), (v) the Consolidated Statements of Cash Flows, and (vi) Notes to the Interim Consolidated Financial Statements.104Cover page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)_____*Â Â Â Â Filed herewith.+Â Â Â Â Furnished herewith.90SIGNATURESPursuant to the requirements of 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.CARISMA THERAPEUTICS INC.Date: NovemberÂ 7, 2024By:/s/ Steven KellySteven KellyPresident, Chief Executive Officer and Director(Principal Executive Officer)Date: NovemberÂ 7, 2024By:/s/ Richard MorrisRichard MorrisChief Financial Officer(Principal Financial and Accounting Officer)91DocumentExhibit 31.1CERTIFICATION PURSUANT TORULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002I, Steven Kelly, certify that:1.I have reviewed this Quarterly Report on Form 10-Q of Carisma Therapeutics Inc.;2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;4.The registrantâ€™s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;(c)Evaluated the effectiveness of the registrantâ€™s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and(d)Disclosed in this report any change in the 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; and5.The registrantâ€™s other certifying officer(s) and I have disclosed, based on our 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: NovemberÂ 7, 2024By:/s/ Steven KellySteven KellyPresident, Chief Executive Officer and Director(Principal Executive Officer)DocumentExhibit 31.2CERTIFICATION PURSUANT TORULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002I, Richard Morris, certify that:1.I have reviewed this Quarterly Report on Form 10-Q of Carisma Therapeutics Inc.;2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;4.The registrantâ€™s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;(c)Evaluated the effectiveness of the registrantâ€™s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and(d)Disclosed in this report any change in the 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; and5.The registrantâ€™s other certifying officer(s) and I have disclosed, based on our 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: NovemberÂ 7, 2024By:/s/ Richard MorrisRichard MorrisChief Financial Officer(Principal Financial and Accounting Officer)DocumentExhibit 32.1CERTIFICATION PURSUANT TO18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TOSECTION 906 OF THE SARBANES-OXLEY ACT OF 2002In connection with the Quarterly Report of Carisma Therapeutics Inc. (the â€œCompanyâ€) on Form 10-Q for the period ended SeptemberÂ 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the â€œReportâ€), I certify, pursuant to 18 U.S.C. Â§ 1350, as adopted pursuant to Â§ 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:(1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and(2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.Date: NovemberÂ 7, 2024By:/s/ Steven KellySteven KellyPresident, Chief Executive Officer and Director(Principal Executive Officer)DocumentExhibit 32.2CERTIFICATION PURSUANT TO18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TOSECTION 906 OF THE SARBANES-OXLEY ACT OF 2002In connection with the Quarterly Report of Carisma Therapeutics Inc. (the â€œCompanyâ€) on Form 10-Q for the period ended SeptemberÂ 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the â€œReportâ€), I certify, pursuant to 18 U.S.C. Â§ 1350, as adopted pursuant to Â§ 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:(1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and(2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.Date: NovemberÂ 7, 2024By:/s/ Richard MorrisRichard MorrisChief Financial Officer(Principal Financial and Accounting Officer)