Risk Factors Comparison 2025-03-07 to 2024-03-28 Form: 10-K

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Investing in our common stock involves a high degree of risk. Investors should carefully consider all of the risk factors and uncertainties described below, in addition to the other information contained in this Annual Report on Form 10- K, including the section of this report titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our consolidated financial statements and related notes, before investing in our common stock. The risks described below may not be the only ones relating to our company and additional risks that we currently believe are immaterial may also affect us. If any of these risks, including those described below, materialize, our business, competitive position, reputation, financial condition, results of operations, cash flows and future prospects could be seriously harmed. In these circumstances, the market price of our securities could decline, and investors may lose all or a part of their investment. Risks Related to Our Financial Results ~~and~~ **,** Capital Needs **, and Review of Strategic Alternatives Our activities to review and pursue strategic alternatives may not result in a strategic transaction, and even if we do consummate a strategic transaction, there is no assurance that it will deliver the benefits we expect or enhance stockholder value. In January 2025, we announced that our board of directors has initiated a process to explore a range of strategic alternatives to maximize value for our stockholders. We previously engaged a well- known financial advisor to support the assessment of opportunities to advance and realize value from our CAR- T assets, for which we announced that we have since paused the CAR T programs and discontinued development operations in March 2025. The advisor' s scope was expanded to include a wider range of additional strategic alternatives, which may include, but are not limited to, an acquisition, merger, reverse merger, other business combinations, sale of assets, or other strategic transactions. We are actively in discussions with several potential parties. We have not set a definitive timetable for completion of this process, and there can be no assurance regarding the results or outcome of this process. It is possible that we may not pursue a strategic alternative as a result of this process, that a strategic alternative that has been pursued may not be attractive, or that a strategic alternative may not ultimately be consummated. As part of the process, our board of directors will consider a full range of strategic alternatives, including, but not limited to, those identified in range of strategic alternative described above. We expect to devote significant time and resources and to incur expenses in identifying and evaluating strategic alternatives for the company, which could have a material adverse effect on our business. A considerable portion of these expenses may be incurred regardless of whether a transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. In addition, potential strategic transactions that require stockholder approval may not be approved by our stockholders or, if required, a counterparty' s stockholders. Further, any strategic transaction that is completed ultimately may not deliver the benefits we expect or enhance stockholder value. Pursuing or consummating any strategic transaction may disrupt our management or business, require us to incur non- recurring or other charges, increase our near- and long- term expenditures, and may pose significant integration challenges, which could adversely affect our operations and financial results. For example, pursuing or consummating these transactions may entail numerous operational and financial risks, including: • the inability to retain our key employees or our other service providers; • increased volatility of our stock price; • higher than anticipated transaction or integration costs; • exposure to unknown liabilities; • write downs of assets or goodwill or impairment charges; • increased amortization expenses; and • the possibility of future litigation. Accordingly, there can be no assurance that we will undertake or successfully complete any strategic transactions of the nature described above and any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, financial condition and prospects. In the event that we do not successfully identify a viable strategic alternative, or consummate such a transaction, or if we are unable to raise sufficient capital to fund our operations, our board of directors may determine to pursue a liquidation and dissolution or other wind down of our business. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities. There can be no assurance that the process to identify strategic alternatives for our business will result in a successfully consummated transaction. If we are unable to identify a viable strategic alternative or if such a transaction is not completed in a timely manner, or if we are unable to raise sufficient capital to fund our operations, our board of directors may determine to pursue a liquidation and dissolution or other wind down of our business. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic options. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our business, we would be required under Delaware law (in addition to paying the costs of the liquidation) to pay our outstanding obligations, as well as to make reasonable provisions for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the satisfaction of such obligations. In addition, we may be subject to litigation or other claims related to a liquidation and dissolution of our business. If a liquidation and dissolution are pursued, our board of directors, in consultation with its legal and financial advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our securities may suffer a total loss of their investment.** We have incurred substantial losses since our inception and anticipate that we will continue to incur

substantial losses for the foreseeable future. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that product candidates will fail to prove effective, gain regulatory approval or become commercially viable. We have one product, Ebvallo, which is approved in the ~~EU and~~ **EEA,** the UK **and Switzerland** and have generated limited revenues from commercialization, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have incurred significant operating losses in every annual reporting period since our inception. For the year ended December 31, ~~2023~~ **2024** , we reported a net loss of $ ~~276~~ **85** . ~~1~~ **4** million. We do not know when, or if, we will generate sufficient revenue from commercialization to offset our operating expenses. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue to research, develop and seek regulatory approvals for our product candidates and any additional product candidates we may acquire, in- license or develop. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of change of our expenses and our ability to generate revenues. If any of our product candidates fails in clinical studies or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our expenses may increase in the future as we continue to invest in research and development of our existing product candidates, investigate and potentially acquire new product candidates. We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights and conducting product development activities for our product candidates. We have not yet demonstrated our ability to successfully complete any Phase 3 clinical studies, obtain regulatory approval in the U. S., consistently manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization for any of our product candidates or arrange for a third party to do so on our behalf. In addition, the adoptive immunotherapy technology underlying our T- cell product candidates, including our next- generation CAR T programs, is new and largely unproven. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving immunotherapy field, may prove to be inaccurate. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We expect our financial condition and operating results to continue 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, any of our quarterly or annual periods' results are not indicative of future operating performance. We have earned limited commercialization revenues to date. We may never achieve profitability. To date, we have generated only limited revenues from commercialization. We have **obtained** regulatory approval for one product, Ebvallo, in the ~~EU~~ **EEA, Switzerland** and the UK. We have out- licensed the commercialization rights to tab- cel (Ebvallo in the ~~EU~~ **EEA, Switzerland** and the UK) to Pierre Fabre under the A & R Commercialization Agreement and we have sold certain royalty and milestone interests for the Initial Territory, subject to a specified cap, to HCRx pursuant to the HCRx Agreement. Our ability to generate revenues from commercialization and achieve profitability will be subject to the A & R Commercialization Agreement, the HCRx Agreement and depend on our commercialization partners' ability to successfully commercialize products, including any of our current product and product candidates, and other product candidates that we may develop, in- license or acquire in the future. Our ability to generate revenues from the sale of products and achieve profitability will also depend on a number of additional factors, including our ability to: • successfully complete development activities, including the necessary clinical studies with positive results; • complete and submit regulatory submissions to the FDA, EMA or other agencies and obtain regulatory approval for indications for which there is a commercial market; • develop manufacturing and distribution processes for our novel T- cell immunotherapy product candidates; • develop commercial quantities of our products, including at acceptable cost levels; • establish and maintain adequate supply of our products, including cell lines with sufficient breadth to treat patients; • establish and maintain manufacturing and commercialization relationships with reliable third parties; • qualify our CMOs' manufacturing facilities such that we can maintain the supply of our products by ensuring adequate manufacturing of bulk drug substances and drug products in a manner that is compliant with global legal and regulatory requirements; • achieve market acceptance of and pricing and reimbursement for our products, if any; • attract, hire and retain qualified personnel; • protect our rights in our intellectual property and regulatory protections portfolio; and • find suitable commercialization partners who can obtain coverage and adequate reimbursement from third parties, including government payors, set commercially viable prices, market, sell and distribute our approved products. Our revenues from Ebvallo or any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and the terms and conditions of our commercialization agreement with our partner for that territory. We do not retain any meaningful milestones or royalty payments from Pierre Fabre for Ebvallo in the Initial Territory until the applicable royalty cap under the HCRx Agreement is met, which could take many years, if at all. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice, treatment guidelines or a reduction in the incidence of the addressable disease, our partners may not successfully commercialize our products, even if approved. The timing and amount of any milestone and royalty payments we may receive from our partners, as well as the commercial success of our products will depend on, among other things, the efforts, allocation of resources, negotiation of pricing and reimbursement and successful commercialization of our products by our partners. As a result, even if we generate product revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations. We will require substantial ~~additional~~ **near- term** financing ~~on terms acceptable~~ to

continue operations ~~us to achieve our goals~~ , and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or manufacturing efforts **, impair our exploration of strategic alternatives, or require us to pursue a liquidation and dissolution or other wind down of our business** . We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of our T- cell immunotherapy product candidates ~~, and the advancement and expansion of our preclinical research pipeline~~ . We also expect to continue to expend resources for the development and manufacturing of our product and product candidates and the technology we have licensed or have an exclusive right to license from our partners. These expenditures will include costs associated with research and development, potentially acquiring or licensing new product candidates or technologies, conducting preclinical and clinical studies and potentially obtaining regulatory approvals and manufacturing products. Under the terms of our license agreements with each of our in- license partners, we are obligated to make payments upon the achievement of certain development, regulatory and commercial milestones. In addition, other unanticipated costs may arise. Because the design and outcome of our ongoing, planned and anticipated clinical studies is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product and product candidates. Our future capital requirements depend on many factors, including: • the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical studies; • the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates, if clinical studies are successful, including any costs from post- market requirements; • the cost of contracting for the manufacture of our product and product candidates for clinical studies in preparation for regulatory approval and in preparation for commercialization; • our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements; • the costs to develop, acquire or in- license future product candidates or technologies; • the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; • the timing, receipt and amount of sales of, or royalties on, our product and future products, if any; and • the emergence of competing technologies or other adverse market developments. We ~~expect~~ **do not believe** that **our** existing cash, cash equivalents and short- term investments **are sufficient to fund our** ~~, combined with certain anticipated payments from the A & R Commercialization Agreement, as well as cost reductions from completed workforce reductions and operating~~ **operations and ongoing** ~~efficiencies resulting from our planned transition of substantially all~~ activities ~~relating~~ **in the near term, and believe that approximately $ 15 million in additional financing is necessary** to **fund our ongoing activities required to achieve BLA approval for** tab- cel ~~at the time of the BLA transfer to Pierre Fabre, will enable us to fund our planned operations into 2027~~ . Such **estimates** ~~anticipated payments~~ are ~~estimates~~ based on assumptions and plans that are subject to change and such changes could materially impact our **expected** cash runway. These assumptions include the receipt of future payments that are dependent upon the successful **transition** ~~filing and approval~~ of ~~the~~ **substantially all activities relating to** tab- cel ~~BLA~~ **to Pierre Fabre by the end of the first quarter of 2025** , as well as the completion of specific development and regulatory activities by us and actions taken by third parties, and are, therefore, uncertain at this time **. Any delay in these transition and other activities will create additional expenses and cash needs for us** . Our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. We do not have any committed external source of funds other than milestone and royalty payments that we may receive under the A & R Commercialization Agreement, subject to the terms of the HCRx Agreement. We do not retain any meaningful milestone or royalty payments related to the Initial Territory from Pierre Fabre until the applicable royalty cap under the HCRx Agreement is met, if at all. As of December 31, ~~2023~~ **2024** , we had total cash, cash equivalents and short- term investments of $ ~~51~~ **42** . ~~7~~ **5** million. Our existing cash, cash equivalents and short- term investments as of December 31, ~~2023~~ **2024** will not be sufficient to fund our planned operations for at least the next twelve months from the date of issuance of these financial statements. These conditions raise substantial doubt about our ability to continue as a going concern for at least 12 months after the issuance of the accompanying consolidated financial statements. To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to secure additional capital, potentially through a combination of public or private security offerings; use of our ATM facility; and / or strategic transactions. We may also need to raise additional funding as required based on the status of our development programs and our projected cash flows. Although we have been successful in raising capital in the past, and expect to continue to raise capital as required, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If we are unable to obtain sufficient funding on acceptable terms, we could be forced to delay, limit, reduce or terminate ~~preclinical studies,~~ clinical studies or other development activities for one or more of our product candidates **, as well as our exploration of strategic alternatives** , which could have a material adverse effect on our business, results of operations, and financial condition. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on terms that are unfavorable to us. We plan to seek required additional capital, and may do so through a variety of means, including through private and public equity offerings and debt financings. For example, in December 2022, we sold certain of our royalty and milestone interests related to the Initial Territory under the ~~amended and restated~~ Pierre Fabre Commercialization Agreement, subject to a specified cap, to HCRx pursuant to the HCRx Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or if existing holders of warrants exercise their rights to purchase common stock, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. To the extent equity valuations, including the trading price of our common stock, are depressed as a result of economic disruptions or other uncertainties, for example due to rising inflationary pressures, the war in Ukraine, the war in the Middle East or other factors, the potential magnitude of this dilution will increase. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, including incurring additional debt, making capital

expenditures, entering into licensing arrangements, or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses or other rights on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development efforts for our product candidates, grant to others the rights to develop and market product candidates that we would otherwise prefer to develop ourselves or take other actions that are adverse to our business. ~~If we fail to continue to meet the listing standards of Nasdaq, our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock. Our common stock is currently listed on the Nasdaq Global Market. Nasdaq has requirements that a company must meet in order to remain listed on Nasdaq. In particular, Nasdaq rules require us to maintain a minimum bid price of $ 1. 00 per share of our common stock (the " Bid Price Requirement "). If the closing bid price of our common stock falls below $ 1. 00 per share for 30 consecutive trading days or we do not meet other listing requirements, we would fail to be in compliance with Nasdaq listing standards. There can be no assurance that we will continue to meet the Bid Price Requirement, or any other requirement in the future. On January 8, 2024, we received a deficiency letter from the Listing Qualifications Department of Nasdaq notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A) (Compliance Period Rule), we have been provided a period of 180 calendar days, or until July 8, 2024 (Compliance Date), to regain compliance with the Bid Price Requirement. If, at any time before the Compliance Date, the bid price for our common stock closes at $ 1. 00 or more for a minimum of 10 consecutive business days, as required under the Compliance Period Rule, Nasdaq will provide us written communication that we have regained compliance with the Bid Price Requirement. If we do not regain compliance with the Bid Price Requirement by the Compliance date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we will be required to (i) transfer to the Nasdaq Capital Market, (ii) provide written notice of our intention to cure the deficiency during the additional 180 calendar day compliance period, by effecting a reverse stock split, if necessary, and (iii) and meet the continued listing requirement for market value of its publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Bid Price Requirement, which requirements include, among other things, a minimum stockholders' equity of at least $ 4 million. For the year ended December 31, 2023, we reported total stockholders' deficit of $ 99. 2 million, which is below the stockholders' equity requirement under the applicable standards. If we do not regain compliance with the Bid Price Requirement by the Compliance Date and we are not eligible for an additional compliance period, or Nasdaq concludes that we will not be able to cure the deficiency during the additional compliance period, Nasdaq will provide us written notification that our common stock will be subject to delisting. At that time, we may appeal the delisting determination to a Nasdaq Hearings Panel. However, there can be no assurance that such appeal would be successful. If the Nasdaq Hearing Panel does not result in Nasdaq granting us an extension of time to achieve compliance with the Minimum Bid Price Rule, our common stock will be delisted from Nasdaq. If our common stock were to be delisted, the actual and potential liquidity of our common stock and our ability to raise future capital would be adversely affected and the market price of our common stock could decrease. If, for any reason, we are unable to obtain listing on another national securities exchange or take action to restore our compliance with Nasdaq' s continued listing requirements, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders: • the liquidity of our common stock; • the market price of our common stock; • our ability to obtain financing for the continuation of our operations; • the number of institutional and general investors that will consider investing in our securities; • the number of market makers in our common stock; • the availability of information concerning the trading prices and volume of our common stock; and ● the number of broker- dealers willing to execute trades in shares of our common stock~~ Our workforce reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business. In August 2022, we reduced our workforce by approximately 20 % across all areas of our company, including members of management. In November 2023, we further reduced our workforce by approximately 30 %. In January 2024, we announced another reduction of our workforce by approximately 25 % **. In January 2025, we announced another reduction of our workforce by approximately 50 %. In March 2025, we further reduced our workforce by approximately 50 %, retaining approximately 35 employees essential to executing on our strategic priorities** . The reductions in force reflect a prioritization around key research and development programs and the reduction of our expense profile. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from restructuring, our operating results and financial condition would be adversely affected. We also cannot be certain that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our cost savings plan may be disruptive to our operations, which could affect our ability to generate product revenue. In addition, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or disruptions in our day- to- day operations. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future, including tab- cel, if approved. There can be no assurance that we will achieve all of the anticipated benefits of the Fujifilm Transaction and we could face unanticipated challenges. We may not realize some or all of the anticipated benefits from the Fujifilm Transaction and we may encounter post- closing risks, including associated with the provision of services to us by FDB pursuant to the Fujifilm MSA. We may experience increased difficulty and loss of institutional knowledge as a result of the transfer of ATOM Facility employees to FDB in connection with the Fujifilm Transaction, which could harm our business. Additionally, significant time and resources may be required from us, which could disrupt our business and distract management from other responsibilities, which may result in losses or continued financial involvement in the ATOM Facility, including through indemnification or other financial arrangements, which could adversely

affect our financial results. Risks Related to the Development of Our Product and Product Candidates We have one approved product, Ebvallo, **which is currently approved** in the ~~EU and~~ **European Economic Area (EEA),** the UK and ~~are generally early in~~ **Switzerland. In March 2025, we announced** our **decision to pause the** development ~~efforts~~ **of our allogeneic CAR T programs** and **discontinue** ~~have only a small~~ -- **all CAR T** ~~number of product candidates in clinical~~ development **operations** . All of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop, manufacture and commercialize our product or product candidates or experience significant delays in doing so, our business may be materially harmed. We have one approved product, Ebvallo, **which is currently approved** in the ~~EU and~~ **EEA,** the UK and **Switzerland** ~~are generally early in our development efforts, and only a small number of our product candidates are in clinical development. The majority of our product candidates are currently in preclinical development~~ . We have invested substantial resources in identifying and developing potential product candidates, conducting preclinical and clinical studies, manufacturing activities, and preparing for the commercial launch of our product and product candidates. Our ability to generate revenues from the sale of our product and product candidates, if approved, will depend heavily on the successful development ~~,~~ **and** manufacture **,** and our partners' eventual commercialization of our product and product candidates. The success of our product and product candidates ~~will depend~~ **depends** on many factors, including the following: • completion of preclinical and clinical studies with positive results, including demonstrating the stability, safety, purity, and potency of our product candidates to the satisfaction of the FDA or other regulatory agencies; • receipt of regulatory approvals from applicable authorities, including required authorizations for clinical trials and marketing authorizations; • protecting our rights in our intellectual property portfolio, including by obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; • establishing or making successful arrangements with third party manufacturers and commercialization partners; • qualifying our and our CMOs' manufacturing facilities for clinical and commercial manufacturing purposes; • developing manufacturing and distribution processes for our novel T- cell product candidates and next- generation CAR T programs; • contracting with third parties for the manufacture of our product candidates at an acceptable cost; • contracting with third parties for commercialization of our products on terms favorable to us, if approved by applicable regulatory authorities; • acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community; • our partners' ability to obtain and maintain coverage and adequate reimbursement by third- party payors, including government payors, for our products, if approved by applicable regulatory authorities; • effectively competing with other therapies; • maintaining a continued acceptable benefit / risk profile of the products following approval; and • maintaining and growing an organization of scientists and functional experts who can develop our products and technology. 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 could materially harm our business. We have been affected by and could be adversely affected in the future by the effects of health epidemics and pandemics, ~~including the COVID- 19 pandemic,~~ which could materially and adversely affect our business and operations in the future, as well as the businesses and operations of third parties on which we rely. Our business could be adversely affected by health epidemics and pandemics ~~, including the COVID- 19 pandemic,~~ which **may** ~~presented~~ -- **present** ~~a~~ substantial public health and economic ~~challenge~~ **challenges** around the world ~~and has affected, and continues to affect, our employees, patients, communities and business operations, as well as the U. S. economy and financial markets. We continue to maintain essential in- person manufacturing and laboratory functions in order to advance key research, development and manufacturing priorities. In connection with these measures, we may be subject to claims based upon, arising out of, or related to COVID- 19 and our actions and responses thereto. The effects of potential future state executive orders, local shelter- in- place orders, government- imposed quarantines, our work- from- home policies and other similar actions may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Further quarantines, shelter- in- place or similar restrictions and other actions taken by foreign, federal, state and local governments, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could be reinstated, related to COVID- 19, other health epidemics and pandemics, or other infectious diseases, could impact our manufacturing capabilities and third party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. In particular, standard transportation channels were impacted and may again be impacted, and we and other manufacturing, testing, product disposition, CMOs and external testing laboratories are subject to enhanced risk assessment and mitigation measures. In addition, there were and may continue to be interruptions in the supply of leukapheresis collections, which supply raw materials used in our products~~ . Our clinical trials may also be affected by health epidemics and pandemics ~~and have been affected by the COVID- 19 pandemic. Clinical site initiation and patient enrollment experienced delays as a result of the COVID- 19 pandemic, including~~ due to ~~the prioritization of hospital resources toward COVID- 19 and away from clinical trials and as a result of changing practice patterns that impact the diseases our trials address. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt~~ **interruptions** ~~healthcare services or if patients are forced~~ to ~~quarantine due to a health epidemic or pandemic. For example, while most clinical trial sites for our studies, including our Phase 3 clinical trial of tab- cel in patients with EBV PTLD, remained open to enrollment for patients, some sites limited the screening and enrollment of new patients due to governmental orders related to COVID- 19, or fear of infection of COVID- 19, limited, and may limit in the future, patients' abilities to access clinical sites. Pandemic- related travel restrictions may also interrupt key clinical trial activities, such as~~ clinical trial site data monitoring and the collection, processing **,** and analyses of efficacy, safety **,** and translational data ~~. For example, at the outset of the COVID- 19 pandemic, we observed a temporary slow- down in stem cell and solid organ transplant volumes, which may have decreased the eligible patient population for the tab- cel Phase 3 study. In April 2020, we initiated a temporary pause in the screening and enrollment of patients in our EMBOLD study of ATA188 in patients with PMS. Although we were able to resume the screening~~

~~and enrollment of patients in our EMBOLD study and enrolled the first patient in the study in June 2020, the COVID- 19 pandemic required us to pause screening and enrollment of patients in our clinical studies~~ . Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to health epidemics and pandemics, may be adversely impacted ~~. In addition, to the extent the COVID- 19 pandemic adversely affected our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this " Risk Factors " section~~ . Our future success is dependent on the ~~regulatory approval~~ **marketing authorization** of our product candidates. We only have one product, Ebvallo, that has gained ~~regulatory~~ **marketing authorization, with** approval **currently** ~~, an approval~~ in the ~~EU and~~ **EEA,** the UK ~~. Currently~~ , ~~our~~ **and Switzerland. Our** prioritized clinical- stage product candidates include tab- cel (tabelecleucel) in the U. S. ~~and ATA3219~~ Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to find a partner who can successfully commercialize our product candidates in a timely manner. Neither we nor our partners can commercialize product candidates in the U. S. without first obtaining ~~regulatory approval~~ **marketing authorization** for the product candidates from the FDA; similarly, neither we nor our partners can commercialize product candidates outside of the U. S. without obtaining ~~regulatory approval~~ **marketing authorization** from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure stability, safety, purity **,** and potency. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical and clinical studies and depends upon numerous factors, including the substantial discretion of the regulatory authorities. The novel nature of our product candidates may create further challenges in obtaining regulatory approval. For example, the FDA and comparable foreign regulatory authorities have limited experience with regulating the development and commercialization of T- cell immunotherapies, particularly allogeneic T- cell product candidates, and CAR T therapies, including assessing the comparability of different versions of such product candidates. In addition, approval policies, regulations, regulatory positions or the type and amount of clinical and other data necessary to gain approval may change during the course of a product candidate' s clinical development and throughout regulatory interactions, and may vary among jurisdictions, particularly for novel therapies. The EC ~~and the MHRA~~ has approved the MAA for Ebvallo as a monotherapy treatment for patients with EBV PTLD who have received at least one prior therapy under " exceptional circumstances, " which is a pathway under which ~~EC and MHRA grant~~ marketing authorization **is granted** when " comprehensive data cannot be obtained even after authorization. " **The MHRA and Swissmedic approved the marketing application for Ebvallo leveraging the EMA assessment.** Under the exceptional circumstances marketing authorization, our commercial partner, Pierre Fabre, is subject to ongoing post- marketing obligations to continue confirmation of the benefits of Ebvallo, and if any of our other product candidates are approved under this pathway, we or our future commercial partners will be subject to this obligation. Continuation of the Ebvallo marketing authorization is subject to annual re- assessment. The annual re- assessment will determine whether the Ebvallo marketing authorization should be maintained, changed, or suspended, based on Pierre Fabre' s fulfillment of post- marketing obligations and the risk / benefit profile of Ebvallo. If we, or our commercial partners, do not satisfy the ongoing post- marketing obligations or the ~~EC determines that the~~ risk / benefit profile of Ebvallo is **determined** not **to be** acceptable **based on new clinical or post- marketing data** , the EC **, MHRA, or Swissmedic** may change or suspend the marketing approval for Ebvallo. We have not obtained regulatory approval for any other product candidate, and it is possible **Ebvallo (tabelecleucel) may not be approved in any other country other than those in which approval has been obtained and also possible** that none of our ~~existing~~ **other** product candidates or any future product candidates will ever obtain regulatory approval. Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including: • disagreement with the design or conduct of our clinical studies; • failure to demonstrate positive benefit / risk profile of the product candidate for its proposed indication; • failure to demonstrate the stability, safety, purity and potency of the product candidate; • failure of clinical sites to conduct the study in accordance with applicable regulatory requirements; • failure of clinical studies to meet the level of statistical significance required for approval; • disagreement with our interpretation of data from preclinical studies or clinical studies; • the insufficiency of data collected from clinical studies of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval; • inability to reach agreement with the FDA or comparable foreign regulatory authorities on the methodologies for, and assessment of, comparability of different versions of product candidates used in non- pivotal studies, pivotal studies and for intended commercial use; • failure to obtain approval of our manufacturing processes or facilities of third party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or • changes or inconsistencies in the requested or required methodologies, statistical analyses, specification criteria or regulatory submission requirements for a product candidate, including changes to, or inconsistencies with, applicable industry practice or precedent; or • changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval or in positions, guidance or feedback communicated by the FDA or comparable foreign regulatory authorities that have a negative impact on the potential approval of a product candidate. The FDA or a comparable foreign regulatory authority may require information beyond what we plan to provide in or expect to be required for a marketing application, including additional CMC information, preclinical or clinical data to support approval. These requirements may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. For example, at a Type B meeting in February 2022, we were not able to align with the FDA on comparability between tab- cel product versions used in the pivotal ALLELE study and the intended commercial product. The FDA initially recommended we conduct a new clinical trial with the commercial product to address the lack of alignment on comparability and to gain additional clinical experience with the intended commercial product. Throughout 2023, we held a number of meetings with the FDA on clinical **and CMC** aspects ~~and~~

~~CMC~~ for a potential BLA submission for tab- cel. ~~We recently~~ **Ultimately, we reached agreement with the FDA on the comparability of tab- cel product manufactured using a different process version with the intended commercial product and subsequently** held a pre- BLA meeting with the FDA that ~~supports~~ **supported** our plan to submit the tab- cel BLA in the second quarter of 2024. The **BLA was submitted in May 2024, and the** FDA ~~may not ultimately accept~~ **accepted the** ~~or approve a~~ BLA submission **in July 2024 and granted priority review** with **a Prescription Drug User Fee Act target action date of January 15, 2025. Although the FDA designated tabelecleucel as a breakthrough therapy, a breakthrough designation (BTD) status is not considered in the FDA' s decision to approve or not approve a product candidate. Designation as a breakthrough therapy is at the discretion of the FDA, and receipt of a BTD designation may not result in a faster development process, review or approval compared to drugs considered for approval under non- expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that the product no longer meets the conditions for qualification and rescind the BTD designation or decide that the time period for FDA review or approval will not be shortened. Furthermore, our CMOs for tab- cel will undergo pre- approval inspection in connection with our tab- cel BLA, and we cannot be certain that we will be able to adequately support them through such inspection nor that they will successfully pass any such inspection. For example, we received the Response Letter from the FDA in January 2025 relating solely to observations during pre- approval inspection of a third- party manufacturing facility in connection with our tab- cel BLA. In addition, in January 2025, the FDA placed a clinical hold on Atara' s active Investigational New Drug (IND) applications. These INDs include the tab- cel program as monotherapy treatment for adult and pediatric patients two years of age and older with Epstein- Barr virus positive post- transplant lymphoproliferative disease (EBV PTLD) and ATA3219 for the treatment of non- Hodgkin' s lymphoma and systemic lupus erythematosus. Some clinical sites that participated in tabelecleucel studies will also undergo inspection, and the FDA may also choose to inspect us as the sponsor of these studies. The FDA ultimately may not approve the BLA for any of the reasons named above or other reasons. If the FDA does not approve the BLA, this could result in a considerable delay to a subsequent BLA submission or could lead us not to pursue a BLA submission at all. For example, the FDA may not approve the BLA based on the data provided, including a concern that** the current clinical dataset **is insufficient** . In this case, the conduct of an additional clinical trial or trials in the lead indication or completing the ongoing ALLELE study may be necessary to support a BLA ~~submission~~ **approval** for tab- cel ~~, which would result in considerable delay to a BLA submission or could lead us not to pursue a BLA submission~~ . Conducting an additional clinical trial, if required, may prove too difficult or too expensive, and the process of designing a **new** clinical trial, enrolling enough patients, and completing treatment and data collection under the protocol could take a significant amount of time, effort, and resources. Even if we complete the clinical trial, the study may not meet its prespecified endpoints, and even if it does, the FDA may still disagree that the clinical trial is sufficient to support submission and approval of a BLA for tab- cel, or may consider that the data, while adequate for BLA ~~submission~~ **approval** , can support only a more limited indication than that for which we initially applied. Our development activities and / or commercialization planning with our partners could be harmed or delayed by governmental or regulatory delays due to a variety of factors. These factors include limitations on the availability of governmental and regulatory agency personnel to review regulatory filings or engage with us (caused by global health concerns or otherwise ~~, including the COVID- 19 pandemic~~); changes to governmental regulatory requirements, policies, guidelines or priorities, reallocation, or availability of government resources; or for other reasons, that may significantly delay the FDA' s, or other regulatory agencies', ability to review and process any submissions we have filed or may file or cause other regulatory delays. If global health concerns ~~continue to~~ prevent the FDA or other regulatory authorities from conducting their regular inspections, or impact reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to review and process our regulatory submissions in a timely fashion, which could have a material adverse effect on our business ~~. For example, in response to the COVID- 19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products inspections of domestic manufacturing facilities through April 2020. On March 18, 2020, the FDA announced its intention to postpone temporarily routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. On July 10, 2020, the FDA announced that it is working toward the goal of restarting on- site inspections it deems to be " mission critical. " In May 2021, the FDA updated its guidance, first published in August 2020, clarifying how it intends to conduct inspections during the COVID- 19 pandemic, including how it plans to determine which inspections are " mission critical. " Additionally, on April 14, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in- person inspection would not be prioritized, deemed mission- critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. The FDA intends to use this risk- based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. The FDA has since adjusted its inspection activities in response to the COVID- 19 pandemic. On December 29, 2021, the FDA implemented temporary changes to its inspection activities to ensure the safety of its employees and regulated firms. On February 2, 2022, FDA announced that it would resume domestic surveillance inspections across all product areas on February 7, 2022. In July 2022, FDA published draft guidance outlining its policies regarding remote regulatory assessments. On May 11, 2023, the COVID- 19 Public Health Emergency (PHE) declared under the Public Health Services (PHS) Act expired. It is unclear how FDA' s and other health agencies' policies and guidance will impact any inspections of our facilities or clinical trial sites involved with our clinical studies~~ . If we do obtain approval for a product candidate marketing application, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval

contingent on the performance of costly post- marketing clinical studies, 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. In addition, the clinical study requirements of the FDA, EMA **, MHRA, Swissmedic,** and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates ~~, such as our novel T- cell product candidates and next- generation CAR T programs~~ , can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the EC and FDA of autologous CAR T therapies, such as Novartis' Kymriah ® and Gilead' s Yescarta ®, may not be indicative of what these regulators ~~may~~ require for approval of our therapies ~~. We have multiple clinical trials of our product candidates currently ongoing~~ . If an adverse safety issue ~~, clinical hold~~ or other adverse finding occurs in one or more of our clinical trials, **including those that could result in a clinical hold,** such ~~event~~ **events** could adversely affect our other clinical trials of the same or related product candidates. Moreover, our product candidates may not perform successfully in clinical studies or may be associated with adverse events that distinguish them from those that have previously been approved, such as approved autologous CAR T therapies. For instance, **exposure to** allogeneic product candidates may result in adverse events not experienced with autologous products. Even if a product candidate is approved by the FDA and comparable foreign regulatory authorities, the approval might contain significant limitations related to use for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post- approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn in a region or country by the respective regulatory agency. Our T- cell immunotherapy product and product candidates ~~and our next- generation CAR T programs~~ represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or our inability to achieve regulatory approval, ~~commercialization~~ **commercialize** or **secure** payor coverage of our product candidates. Our future success is dependent on the successful development and commercialization of T- cell immunotherapies ~~and our next- generation CAR T programs~~ in general and our development product candidates in particular. Because these programs, particularly our pipeline of allogeneic T- cell product and product candidates that are bioengineered from donors, represent a new approach to immunotherapy for the treatment of cancer and other diseases, developing and commercializing our product candidates subject us to a number of challenges, including **but not limited to** : • obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of T- cell immunotherapies, particularly allogeneic T- cell products and product candidates; • developing and deploying consistent and reliable processes for procuring blood from consenting third party donors, isolating T cells from the blood of such donors, activating the isolated T cells against a specific antigen, characterizing and storing the resulting activated T cells for future therapeutic use, selecting and delivering a sufficient supply and breadth of appropriate partially HLA- matched cell line from among the available T- cell lines, and finally infusing these activated T cells into patients; • utilizing these product candidates in combination with other therapies (e. g., immunomodulatory approaches such as checkpoint inhibitors), which may increase the risk of adverse side effects; • educating medical personnel regarding the potential side effect profile of our product and each of our product candidates, particularly those that may be unique to our allogeneic T- cell product and product candidates ~~and to our next- generation CAR T programs~~ ; • understanding and addressing variability in the quality of a donor' s T cells, which could ultimately affect our ability to manufacture products and product candidates in a reliable and consistent manner; • developing processes for the safe administration of these product and product candidates, including long- term follow- up and registries, for all patients who receive these product candidates; • establishing or making arrangements with third party manufacturers to manufacture, or manufacturing on our own, product and product candidates to our specifications and in a timely manner to support our clinical studies and, if approved, commercialization; • sourcing clinical and, if approved by applicable regulatory authorities, commercial supplies for the materials used to manufacture and process these product and product candidates that are free from viruses and other pathogens that may increase the risk of adverse side effects; • developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment; • establishing favorable terms with commercialization partners that possess appropriate sales and marketing capabilities ahead of and after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third party payors and government authorities; and • developing therapies for types of diseases beyond those initially addressed by our current product and product candidates. We cannot be sure that the manufacturing processes used in connection with our T- cell immunotherapy product and product candidates will yield a sufficient supply of satisfactory products that are stable, safe, pure, and potent, or comparable to those T cells historically produced by our partners ~~,~~ **or that processes will** be scalable or profitable. Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical studies, or, if one of our product candidates is approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics or of patients to provide consent to receive a novel treatment despite its regulatory approval. The FDA or other applicable regulatory authorities may require specific post- market studies or additional information that communicates the benefits or risks of our products. New data may reveal new risks of our product candidates at any time prior to or after regulatory approval. ~~The FDA~~ **Furthermore, regulatory agencies** may also modify or enhance trial requirements which may affect enrollment. ~~In~~ **For example, in** August 2023, the FDA published a guidance document **entitled** , Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. The FDA' s new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical

trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial and could cause a significant setback to an applicable program. Physicians, hospitals and third party payors often are slow to utilize new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training on this novel therapy, may decide the therapy is too complex to adopt without appropriate training or not cost- efficient, and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs. The results of preclinical studies or earlier clinical studies are not necessarily predictive of future results. Our existing product ~~candidates~~ **candidate** in clinical studies, and any other product candidate we advance into clinical studies, may not have favorable results in later clinical studies or receive regulatory approval. Success in preclinical studies and early clinical studies does not ensure that later clinical studies will generate adequate data to demonstrate the efficacy and safety of an investigational drug. ~~Likewise~~ **Indeed**, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical studies, even after seeing promising results in earlier preclinical studies or clinical studies. Despite the results reported in earlier preclinical studies or clinical studies for our product candidates, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors. We do not know whether the clinical studies we may conduct, or clinical studies in progress, will demonstrate adequate efficacy and safety to result in regulatory approval to market any product candidates in any particular jurisdiction. Tab- cel has been predominantly evaluated in single- center studies under investigator- sponsored ~~investigational new drug (INDs~~ **IND** ~~)~~ applications held by MSK and in our Expanded Access Programs, utilizing different response criteria and endpoints from those we have used or may utilize in later clinical studies. These Phase 2 clinical studies with tab- cel also enrolled a heterogeneous group of patients with a variety of EBV- driven malignancies, including EBV PTLD after HCT and EBV PTLD after SOT. These Phase 2 studies were not prospectively designed to evaluate the efficacy of tab- cel in the treatment of a single disease state for which we may later seek approval. Findings from early studies may not be reproducible in late phase studies we conduct. For instance, the current protocol for our ALLELE study in EBV PTLD is designed to rule out a 20 % ORR as the null hypothesis. This means that if the lower bound of the 95 % confidence interval on ORR among patients receiving at least one dose of tab- cel exceeds 20 % at the end of the study, then the study would be expected to meet the primary endpoint for the treatment of PTLD. ~~For example, assuming~~ **Assuming** enrollment of 33 patients in a cohort of ALLELE, an observed ORR above approximately 37 % would be expected to meet the primary endpoint for that cohort. In addition, our amended ALLELE study protocol includes an interim analysis as well as a final study analysis. We have previously received feedback from the FDA that an interim analysis of the ALLELE study may not be sufficient to support approval of a BLA. Moreover, final study results may not be consistent with interim study results. Furthermore, modifications to the total sample size of the ALLELE study and the statistical approach may be necessary in connection with the review of **the** ~~such a~~ BLA ~~submission~~ by the FDA. Efficacy data from prospectively designed studies may differ significantly from those obtained from retrospective subgroup analyses. In addition, clinical data obtained from a clinical study with an allogeneic product candidate may not yield the same or better results as compared to an autologous product candidate. If later- stage clinical studies do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical studies. ~~Ebvallo was approved under the exceptional circumstances regulatory pathway by the EMA and the MHRA, therefore continuation of the Ebvallo marketing authorizations in the EU and the UK are subject to annual reassessments. The annual reassessments will determine whether the Ebvallo marketing authorization should be maintained, changed, or suspended, based on Pierre Fabre' s fulfillment of post- marketing obligations and the risk / benefit profile of Ebvallo.~~ Interim " top line " and preliminary data from clinical studies that we or our partners may announce or share with regulatory authorities from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we or our partners may announce or share with regulatory authorities interim " top line " or preliminary data from clinical studies. Interim data from clinical studies are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or " top line " data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously announced. 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 impact the regulatory approval of, and **/ or** significantly harm the prospects of any product candidate that is impacted by the applicable data. Clinical drug development involves a lengthy and expensive process with an uncertain outcome. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through preclinical and clinical studies. We may experience delays in our ongoing or future clinical studies and we do not know whether clinical studies will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA or comparable foreign regulatory authorities will not put clinical studies of any of our product candidates on clinical hold in the future **. For example, in January 2025, the FDA placed a clinical hold on our INDs for tab- cel as well as our product candidate ATA3219. The clinical hold is directly linked to inadequately addressed GMP compliance issues identified during the pre- approval inspection of a third party manufacturing facility referenced in a Response Letter we received in January 2025. Our ATA3219 product candidate is manufactured at a separate, fully compliant GMP- certified facility, the starting material used in its production are affected by the compliance issues at the same third- party facility referenced in the Response Letter. In addition, the new EU Clinical Trials Regulation (EU) No 536 / 2014 (CTR) has amended the system of approval for clinical trials in the EU and has established a new clinical**

trials portal and database, called the Clinical Trials Information System (CTIS), for the submission and authorization of clinical trial applications . Clinical studies may be delayed, suspended or prematurely terminated for a variety of reasons, such as: • delays in enrollment due to travel, shelter- in- place or quarantine policies, or other factors, related to the COVID- 19 pandemic or other epidemics or pandemics; • delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a study design that we are able to execute; • delay or failure in obtaining authorization to commence a study or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a study; • delay or failure in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites; • delay or failure in obtaining institutional review board (IRB) approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical study at each site; • withdrawal of clinical study sites from our clinical studies or the ineligibility of a site to participate in our clinical studies; • delay or failure in recruiting and enrolling eligible subjects to participate in a study; • delay or failure in subjects completing a study or returning for post- treatment follow- up; • clinical sites and investigators deviating from study protocol, failing to conduct the study in accordance with regulatory requirements, or dropping out of a study; • an FDA or other regulatory authority clinical site inspection ~~reveals~~ **revealing** serious violations of regulations applicable to clinical investigations, which may result in requests for additional data analyses and / or rejection of data deemed unreliable; • inability to identify and maintain a sufficient number of study sites, including because potential study sites may already be engaged in competing clinical study programs enrolling the same population; • failure of our third- party clinical study managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data; • delay or failure in adding new study sites; • interim results or data that are ambiguous or negative or are inconsistent with earlier results or data; • feedback from the FDA, the IRB, data safety monitoring boards or comparable foreign authorities, or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to ~~the~~ **a study** protocol ~~for a study~~ ; • a decision by the FDA, the IRB, comparable foreign authorities, or us, or a recommendation by a data safety monitoring board or comparable foreign authority, to suspend or terminate clinical studies for non- compliance with regulatory requirements, safety issues, including a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risk, or for any other reason; • **data that demonstrate an** unacceptable benefit / risk profile, **including a lack of efficacy,** unforeseen safety issues or adverse side effects ~~; • failure to demonstrate a benefit from using a product candidate; •~~ difficulties in manufacturing or obtaining from third parties sufficient quantities **of clinical product** and **/ or inability to supply a** breadth of appropriate partially HLA matched cell lines from among the available T- cell lines to start or to use in clinical studies; • lack of adequate funding to continue a study, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties **; • non- compliance with CTIS processes under the new EU Clinical Trial Regulation, including with the CTIS transparency rules, which became applicable on June 18, 2024 and which will require adapting business processes of clinical trial sponsors** ; or • changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical study. Patient enrollment, a significant factor in the timing of clinical studies, is affected by many factors including: • the size and nature of the patient population; • the possibility that the rare diseases that many of our product candidates address are under- diagnosed; • changing medical practice patterns or guidelines related to the diseases or conditions we are investigating; • the severity of the disease under investigation; • our ability to open clinical study sites; • the proximity of subjects to clinical sites; • the patient referral practices of physicians; • the design and eligibility criteria of the clinical study; • ability to obtain and maintain patient consents; • risk that enrolled subjects will drop out or die before completion; • competition for patients from other clinical studies; • our or our partner' s ability to manufacture the requisite materials for a study; • risk that we do not have appropriately matched HLA cell lines; • clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the diseases or conditions we are investigating; and • disruptions caused by man- made or natural disasters or public health pandemics or epidemics, including, for example, the COVID- 19 pandemic. As an example, we activated additional clinical sites for the ALLELE study of tab- cel over the course of 2018 and increased HLA coverage during this period. As a result, enrollment in our studies was limited in the early part of 2018 and increased through the course of the year as we increased clinical sites and HLA coverage. However, in May 2019, we announced that enrollment in our Phase 3 studies of tab- cel for patients with EBV PTLD was proceeding slower than anticipated. Many of our product candidates are designed to treat rare diseases, and as a result, the pool of potential patients with respect to a given disease is small. We may not be able to initiate or continue to support clinical studies of tab- cel or any other product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these studies as required by the FDA or other regulatory authorities. We experienced some transient delays in clinical trial site initiation and patient enrollment in certain of our clinical trials, including our ALLELE study, as a result of the COVID- 19 pandemic. Even if we are able to enroll a sufficient number of patients in our clinical studies, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our studies may be delayed or our studies could become too expensive to complete. We rely on CROs, other vendors and clinical study sites to ensure the proper and timely conduct of our clinical studies, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Reliance on CROs entails risks to which we would not be subject if we conducted our clinical studies ourselves, including reliance on the CRO for clinical site initiation and monitoring, the possibility that the CRO does not maintain the financial resources to meet its obligations under our agreements, the possibility of breach of these agreements by the CRO because of factors beyond our control, including a failure to properly perform their obligations under these agreements, and the possibility of termination or non- renewal of the agreements by the CROs, based on their own business priorities, at a

time that is costly or damaging to us. **For example, the CRL MSA expired on August 31, 2024 and we are in negotiations to wind- down our activities at CRL. We are exploring other options for the manufacture of our product and product candidates. There can be no assurance that we will be able to find a new CMO or enter into a new commercial drug product supply agreement with a new CMO on terms favorable or acceptable to us or at all. Any delays in entering into a new commercial manufacturing agreement could delay the development and commercialization of our product and product candidates, if approved.** Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan, study protocols for the trial, statistical analysis plan and other study- specific documents (for example, monitoring and blinding plans). Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practice (GCP), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines, and regulations regarding the informed consent process, safety reporting requirements, data collection guidelines, and other regulations 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. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP and other applicable regulations. In addition, our clinical trials must be conducted with product produced under applicable current Good Manufacturing Practices (cGMP) and current Good Tissue Practices (cGTP) regulations. Our **, or our third party vendors',** failure to comply with these regulations may require us to conduct new clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on ~~a~~ government- sponsored ~~database~~ **databases** , **such as** ClinicalTrials. gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we experience delays or quality issues in the conduct, completion or termination of any clinical study of our product candidates, the approval and commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical studies will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to generate revenues. Any delays in completing our clinical studies for our product candidates may also decrease the period of commercial exclusivity. In addition, many of the factors that could cause a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. Our product and product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval. Undesirable side effects caused by our product and product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we or our partners may experience in our clinical studies, we or our partners may not receive approval to market any product candidates, which could prevent us from ever generating product or royalty revenues for such product candidates or achieving profitability. Results of our studies could reveal an unacceptably high severity and incidence of side effects, or risks that outweigh the benefits of our product and product candidates. In such an event, our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled subjects to complete the study or result in potential product liability claims. Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that: • we may be forced to suspend marketing of that product; • regulatory authorities, IRBs, or other clinical trial oversight bodies may place a hold on any ongoing clinical trials; • regulatory authorities may withdraw or change their approvals of that product; • regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment; • we may be required to conduct post- marketing studies; • we may be required to change the way the product is administered; • we could be sued and held liable for harm caused to subjects or patients; • our products may be seized, or we may be required to recall our products; • our products may become less competitive in the marketplace; and • our reputation may suffer. Any of these events could diminish the usage or otherwise limit the commercial success of our product and product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities. The market opportunities for our product and product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small. The FDA often approves new cancer therapies initially only for use in patients with relapsed or refractory metastatic disease. We expect to seek initial approval of tab- cel and our other oncology product candidates in this setting. Subsequently, for those products that prove to be sufficiently beneficial, if any, we may seek approval for earlier lines of treatment and potentially as a first line therapy, but there is no guarantee that our product and product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we will have to conduct additional clinical trials. Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases in a position to receive second or later lines of therapy, and

who have the potential to benefit from treatment with our product and product candidates, are based on our current beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinicians, patient foundations, or our own market research, and may prove to be incorrect. Further, new studies, product approvals, changes to the standard of care and diagnosis rates or scientific understanding of disease burden may change the estimated incidence or prevalence of these diseases, and the number of patients who could benefit from our products may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, **for** ~~we expect~~ our product, tab- cel, ~~to~~ **we have** initially ~~target~~ **pursued marketing authorization for** a patient population that suffers from aggressive EBV PTLD and has failed rituximab or rituximab plus chemotherapy. Our commercial partners may have different estimates of the market opportunities for our product or product candidates. At the outset of the COVID- 19 pandemic, we initially observed a temporary slow- down in stem cell and solid organ transplant volumes. These reductions were transient, but if a reduction in such volumes resumes or if there are other disruptive factors that reduce PTLD incidence, such as changes in immunosuppression regimens or treatment of re- activated viremia, it could result in lower PTLD incidence and thus reduce the demand for tab- cel. Even if our product and product candidates obtain significant market share, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. We may not be able to obtain or maintain orphan drug exclusivity for our product candidates. Regulatory authorities in some jurisdictions, including the U. S., EU and the UK, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the U. S. The FDA, the EMA, and the MHRA have granted us orphan drug designation for tab- cel for EBV PTLD. Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA, the EMA, and the MHRA from approving another marketing application for the same biologic for the same indication for that time period. The applicable period is seven years in the U. S. and ten years in the EU and the UK. The EU and UK exclusivity periods can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. These periods may be reduced in the EU based on a new applicable legal framework, currently under review by the European Parliament and Council. Orphan drug exclusivity may be lost if the FDA, EMA or MHRA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In the U. S., the FDA may still approve a later marketing application blocked by an ongoing period of orphan drug exclusivity in limited circumstances such as a ~~showing~~ **demonstration** of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was approved. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve or license other drugs or biological products that have a different active ingredient for use in treating the same indication or disease. In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a 2021 ~~11th Circuit~~ **11thCircuit** decision, Catalyst Pharms., Inc. v. Becerra, 14 F. 4th 1299 (11th Cir. 2021), in which the court disagreed with the FDA' s longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease, and not to all uses or indications within the entire disease or condition. In particular, the circuit court held that that the orphan- drug exclusivity for the drug developed by Catalyst Pharmaceuticals, Inc. (Catalyst) blocked the FDA' s approval of another drug for all uses or indications within the same orphan- designated disease, Lambert- Eaton myasthenic syndrome (LEMS), even though Catalyst' s drug was approved at that time only for use in the treatment of LEMS in adults. Accordingly, the court ordered the FDA to set aside the approval of a drug indicated for LEMS in children. This decision created uncertainty in ~~the~~ application of ~~the~~ orphan drug exclusivity **to products on the market** . Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and could materially adversely affect our business, financial condition, results of operations, cash flows and prospect. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not be maintained or effectively protect the product from competition because different drugs can be approved for the same condition. BTD by the FDA and PRIME designation by the EMA may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. **We** ~~Although we~~ have obtained BTD for tab- cel in the U. S. for treatment of patients with EBV PTLD who have failed rituximab, ~~these~~ **however this** ~~designations~~ **designation** may not lead to faster development or regulatory review and does not increase our likelihood of success. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic in our case, 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 product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the study can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for other expedited review programs, such as priority review. ~~Based on our~~ **Even though the FDA may grant priority review of a marketing application for a product granted** BTD, **BTD status is not considered** ~~we may pursue a rolling submission strategy for our BLA for tab- cel for EBV PTLD~~ in ~~the U. S. While a rolling review process may provide the opportunity for ongoing communications with and feedback from~~ the FDA ~~, it may~~ **' s decision to approve or** not ~~result in a faster timeline to marketing approval and has no bearing on whether or not tab- cel is ultimately approved~~ **approve** ~~. The FDA may raise issues and pose questions to us that may delay the initiation~~

~~and completion of our BLA submission, acceptance of the complete BLA for filing, and approval of the BLA. We may not be able to provide~~ a **product candidate** ~~satisfactory or a timely response to FDA questions or we may not be able to gather the required data to prepare our BLA submissions as we plan. If we are unable to address all questions or concerns that the FDA may raise or if we do not have timely access to the data required for the preparation of the BLA, we may not be able to initiate and complete our BLA in a timely manner and ultimately receive FDA approval. In addition, even if we submit our BLA under the rolling review process, the FDA may decide not to review portions of our BLA under the rolling review process until the submission is deemed to be complete~~ . PRIME designation supports the development and accelerated review by the EMA of new therapies to treat patients with unmet medical need. Despite this designation and the associated opportunity for accelerated assessment, the EMA may decide that additional time is needed for the MAA review and convert the MAA to a standard review timeline. For example, the EMA converted the tab- cel MAA review timeline from accelerated to standard **, despite tab- cel' s PRIME designation** . Designation as a breakthrough therapy is at the discretion of the FDA, and access to PRIME is at the discretion of the EMA. Receipt of a BTD or PRIME designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non- expedited FDA or EMA review procedures and does not assure ultimate approval by either the FDA or EMA. In addition, the FDA or EMA, respectively, may later decide that the product no longer meets the conditions for qualification and rescind the BTD or PRIME designation or decide that the time period for FDA or EMA, respectively, review or approval will not be shortened. For example, in June 2022, FDA published a draft guidance document outlining considerations for the FDA in rescinding BTD for products that no longer meet the requirements for that designation. A Fast Track designation by the FDA ~~, even if granted for other current or future product candidates,~~ may not lead to a faster development or regulatory review, licensure process and does not increase the likelihood that our product candidates will receive marketing licensure. We may seek fast track designation for one or more of our future product candidates. If a drug or biological product is intended 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, the drug sponsor may apply for FDA fast track designation for a particular indication. We may seek fast track designation for our product candidates, but there is no assurance that the FDA will grant this designation to any of our proposed product candidates **, even if such a designation has been granted to similar products** . Marketing applications submitted by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification or ultimate marketing licensure by the FDA. The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or licensure compared to conventional FDA procedures or pathways and receiving a fast track designation does not provide assurance of ultimate FDA licensure. In addition, the FDA may withdraw fast track designation at any time, including if it believes that the designation is no longer supported by data from our clinical development program. Failure to obtain regulatory or payor approval in international jurisdictions would prevent our product candidates from being marketed abroad. In addition to regulations in the U. S., to market and sell our products in the EU, the UK, many Asian countries and other jurisdictions, we, or our current or future commercialization partners, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. 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 regulatory approval process outside the U. S. generally includes all of the risks associated with obtaining FDA approval and may include additional risks. Clinical studies accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the U. S. require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We or our partners may not be able to obtain approvals from regulatory authorities or payor authorities outside the U. S. on a timely basis, if at all. Approval by a regulatory agency or payor does not ensure approval by any other regulatory or payor authorities in other countries or jurisdictions. We may not be able to file for regulatory approvals and may not receive **the approvals** necessary ~~approvals~~ to commercialize our products in any market. If we or our partners are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the US, EU, the UK, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished. The proposed revision of the European legislation on pharmaceuticals **, changes in governmental administration or changes in leadership at relevant agencies** could lead to uncertainties over the regulatory framework that will be applicable to medicinal products in the EU **and US** , including orphan medicinal products. In April 2023, the EC published proposals to revise the existing European legislation on medicinal products (EU Pharma Law Review). The revisions consist of two proposals, a new directive and a new regulation (EU Pharma Law Proposal) that would amend and / or repeal and replace the relevant legislation concerning medicinal products for human use, including legislation concerning orphan medicinal products and medicinal products for pediatric use. The EU ~~pharma~~ **Pharma** Law Review could have a significant impact on the designation of and incentives offered to orphan medicinal products in the EU. If adopted in current form, the EU Pharma Law Proposal would introduce the possibility for the ~~Commission~~ **EC** , by way of delegated acts, to derogate from the current prevalence criterion, and introduce specific criteria for certain conditions, due to the characteristics of such conditions or other scientific reasons. The EU Pharma Law Proposal also proposes changes to the current orphan market exclusivity (OME) approach. If adopted in the current form, the EU Pharma Law Proposal would in most cases reduce the duration of the OME and replace the current system of separate OME periods for each new indication with a system with a single OME period for each active substance. Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties. Even if we, or our partners obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the

manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post- marketing information. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance by us and / or our CMOs and CROs for any post- approval clinical studies that we conduct **and for continued commercialization of the product** . They also include any post- approval requirements or commitments imposed by FDA or comparable foreign regulatory authorities as a condition of approval, **and /** or any risk evaluation or mitigation strategies (REMS), if applicable. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on a product' s indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies or post- market surveillance. In addition, manufacturers of drug products and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMP, current GCP, current cGTP and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured **or materials for the product manufacture are sourced** , a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our products, product candidates, or the manufacturing facilities for our products or product candidates fail to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters or untitled letters; • mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners; • require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; • seek an injunction or impose civil or criminal penalties or monetary fines; • suspend, withdraw or modify regulatory approval; • suspend or modify any ongoing clinical studies; • refuse to approve pending applications or supplements to applications filed by us; • suspend or impose restrictions on operations, including costly new manufacturing requirements; or • seize or detain products, refuse to permit the import or export of products, require us to withdraw product from the market, or require us to initiate a product recall. The occurrence of any event or penalty described above may also generate negative publicity or inhibit our ability to successfully commercialize our products. Advertising and promotion of any product candidate that obtains approval in the U. S. will be heavily scrutinized by the FDA, the Department of Justice (DOJ), the Office of Inspector General of the Department of Health and Human Services (HHS), state attorneys general, members of the U. S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U. S. will be heavily scrutinized by comparable foreign entities and stakeholders. For example, a company may not promote " off- label " uses for its drug products. An off- label use is the use of a product for an indication that is not described in the product' s FDA- approved label in the U. S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off- label uses. Although the FDA and other regulatory agencies do not regulate a physician' s choice of drug treatment made in the physician' s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off- label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product' s FDA approved labeling. Violations, including actual or alleged promotion of our products for unapproved or off- label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties. **Changes to** ~~Regulations~~ **regulations** , guidelines and recommendations published by various government agencies and organizations may affect the use of our product candidates. Changes to regulations, recommendations or other guidelines advocating alternative therapies for the indications we treat could result in decreased use of our products. For example, although treatment with EBV- specific T cells is recognized as a recommended treatment for persistent or progressive EBV PTLD as set forth in the National Comprehensive Cancer Network Guidelines, future guidelines from governmental agencies, professional societies, practice management groups, private health / science foundations and other organizations could lead to decreased ability to develop our product candidates, or decreased use of our products once approved by applicable regulatory authorities. We may not successfully identify, acquire, develop or commercialize new potential product candidates. Part of our business strategy is to expand our product candidate pipeline by identifying and validating new product candidates, which we may develop ourselves, in- license or otherwise acquire from others. In addition, in the event that our existing product candidates do not receive regulatory approval or are not successfully commercialized, then the success of our business will depend on our ability to expand our product pipeline through internal development, in- licensing or other acquisitions. We may be unable to identify relevant product candidates. If we do identify such product candidates, we may be unable to reach acceptable terms with any third party from which we desire to in- license or acquire them. Any product candidates we identify, acquire, in- license, develop, or manufacture may not be safe or effective for their targeted diseases, and may not receive marketing authorization in a timely manner, or at all. Risks Related to Manufacturing We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product and product candidates. Concurrently with the in- license of our existing product and product candidates, we acquired manufacturing process know- how and, in some cases, inventory of process intermediates and clinical materials from our partners. Transferring manufacturing processes, testing and associated know- how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes and / or equipment to meet the specific requirements of a given

facility. Each stage is retroactively and concurrently verified to be compliant with appropriate regulations. As a result, there is a risk that all relevant know- how was not adequately transferred to us from our partners or that previous execution was not compliant with applicable regulations. In addition, we need to conduct significant development and scale- up work to transfer these processes and manufacture each of our product and product candidates for various studies, clinical studies and commercial launch readiness. To the extent we elect to transfer manufacturing within our network of third party CMOs, we are required to demonstrate that the product manufactured in the new or " receiving " facility is comparable **and / or non- inferior** to the product manufactured in the original or " sending " facility. The inability to demonstrate to each of the applicable regulatory authorities that ~~comparable~~ **acceptable** drug product was manufactured could delay the development of our product candidates or availability of additional commercial product supplies. The processes by which some of our product and product candidates are manufactured were initially developed by our partners for clinical purposes. We intend to evolve the processes developed by our partners and the processes developed by us to support advanced clinical studies and commercialization requirements. We similarly intend to evolve the processes originating at Atara to support advanced clinical studies and commercialization requirements. Developing commercially viable manufacturing processes is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical studies or commercialization, including cost overruns, potential problems with process scale- up, process reproducibility, comparability issues, stability, safety, purity and potency issues, regulatory agency review and endorsement processes, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product and product candidates will be made could be adversely affected by pandemics, earthquakes and other natural or man- made disasters, equipment failures, labor shortages, power failures, and numerous other factors. In addition, there have been, and there may continue to be, transient interruptions in the supply of raw materials and consumables used in the development and manufacturing of our preclinical and clinical cell therapies related to raw material shortages due to the COVID- 19 pandemic or other global pressures, including leukapheresis collections, which supply starting materials used in our product and product candidates, and raw materials and consumables specialized for cell therapy manufacturing. If we are unable to obtain such raw materials or other necessary raw materials in a timely manner, our business operations and manufacturing capabilities could be adversely affected. The process of manufacturing cellular therapies is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product and product candidates could result in reduced production yields, impact to key product quality attributes, and other supply disruptions. Product defects can also occur unexpectedly. If microbial, viral or other contamination is discovered in reagents or in our product ~~and~~ **or** product candidates or in the manufacturing facilities in which our product and product candidates are made, these manufacturing facilities may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. For example, we ~~were~~ **have been** informed by a CMO of mold **and other** contamination in certain manufacturing suites related to the manufacture of finished Ebvallo and tab- cel product and intermediates at the CMO' s facility **. We have had to,** and ~~we~~ **may in the future need to, pause certain manufacturing activity at this CMO. We continue to** ~~worked~~ -- **work** with the CMO to investigate and remediate **contamination issues but can make no assurance regarding** such **remediation efforts** ~~contamination issue while production continued in other manufacturing suites~~. Because our T- cell immunotherapy product and product candidates are manufactured from cells collected from the blood of third party donors, the process of manufacturing is susceptible to the availability of the third party donor material. The process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product and product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product and product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process **, which can be weeks** . Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. Viral contaminants may also arise in recombinant viral reagent production systems used to manufacture viral reagents used to manufacture product and product candidates. These types of ~~contaminations~~ - **contamination** could result in delays in the manufacture of products which could result in delays in the development of our product candidates. ~~These contaminations~~ - **Contamination** could also increase the risk of adverse side effects. Furthermore, our allogeneic products ultimately consist of many individual cell intermediate or cell product lots, each with a different HLA profile. As a result, the selection and distribution of the appropriate cell product lot for therapeutic use in a patient requires close coordination between clinical operations, supply chain and quality assurance personnel. Any adverse developments affecting our, or our CMOs' manufacturing operations for our product and product candidates may result in lot failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in the supply of our drug product which could delay the development of our product candidates or our ability to supply product to our commercial partners, including Pierre Fabre. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our product and product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics. Delays in receiving regulatory approvals for product candidates produced at our CMOs' facilities could delay our development plans and thereby limit our ability to generate revenues. The research and development and process and analytical development labs within ARC and our facility in Aurora, Colorado, currently support our ~~preclinical and~~ mid / late development activities. Product- specific qualification to support clinical development and commercial production qualification activities are ongoing for product candidates at our CMOs' facilities. If the appropriate regulatory approvals for manufacturing product candidates at our CMOs' facilities are delayed, we may not be able to manufacture sufficient quantities

of our product candidates, which would **negatively impact commercial supply,** limit our development activities and **limit** our opportunities for growth. In addition to the similar manufacturing risks described in " Risks Related to Our Dependence on Third Parties, " our facilities, and our CMOs' facilities, will be subject to ongoing, periodic inspection by the FDA, EMA or other comparable regulatory agencies to ensure compliance with cGMP and GTP. Our, or our ~~partner~~ **partners '** ~~' s~~, failure to follow and document adherence to these regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or ~~, in the future,~~ commercial use, may result in the termination of or a hold on a clinical study, or may delay or prevent filing or approval of commercial marketing applications for our product candidates **. For example, in January 2025, we received the Response Letter from the FDA relating solely to observations during pre- approval inspection of a third- party manufacturing facility in connection with our tab- cel BLA. The FDA also placed a clinical hold on our INDs for tab- cel as well as our product candidate ATA3219. The clinical hold is directly linked to inadequately addressed GMP compliance issues identified during the pre- approval inspection of a third party manufacturing facility referenced in the Response Letter we received in January 2025. Although our ATA3219 product candidate is manufactured at a separate, fully compliant GMP- certified facility, the starting materials used in its production are affected by the compliance issues at the same third- party facility referenced in the Response Letter** . We also may encounter problems with the following: • achieving adequate inventory of clinical- grade materials that meet regulatory agency standards or specifications with consistent and acceptable production yield and costs; • shortages of qualified personnel, raw materials or key contractors; and • achieving and maintaining ongoing compliance with cGMP regulations and other requirements of the FDA, EMA or other comparable regulatory agencies. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical studies, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could harm our business. Developing advanced manufacturing techniques and process controls is costly, time consuming and is required to fully utilize our or our CMOs' facilities. Failure to advance manufacturing techniques and process controls could lead to a delay in obtaining approval for our product candidates. Without further investment, advances in manufacturing techniques may render the facilities and equipment that manufacture our product candidates inadequate or obsolete. A number of the product candidates in our portfolio, if approved by applicable regulatory authorities, may require significant commercial supply to meet market demand. In these cases, we may need to increase, or " scale up, " the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third party supplier, we may not be able to produce our product candidates in sufficient quantities to meet future demand. If one or more of our CMO' s facilities is damaged or destroyed or production at these facilities is otherwise interrupted, our business would be negatively affected. If any of our CMOs' manufacturing facilities, or the equipment in any such facilities, is either damaged or destroyed, we may not be able to quickly or inexpensively replace such manufacturing capacity or replace it at all. In the event of a temporary or protracted disruption in operations or loss of a facility or its equipment, we may not be able to transfer manufacturing to another third party in the time required to maintain supply. Even if we could transfer manufacturing to another third party, the shift would likely be expensive and time- consuming, particularly since the new facility would need to comply with the necessary regulatory requirements or may require regulatory approval before selling any products manufactured at that facility. Such an event could delay our clinical studies or reduce our commercial product revenues. Currently, we maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes. Maintaining clinical and commercial timelines is dependent on our end- to- end supply chain network to support manufacturing; if we experience problems with our third party suppliers or CMOs **,** we may delay development and / or commercialization of our product and product candidates. We rely on our CMOs or our partners for the current production of our product and product candidates and the acquisition of materials incorporated in or used in the manufacturing or testing of our product and product candidates. Our CMOs or partners are not our employees, and except for remedies available to us under our agreements with our CMOs or partners, we cannot directly control whether or not they devote sufficient time and resources, including experienced staff, to the manufacturing of supply for our ongoing clinical, nonclinical and preclinical programs **and commercial product** . Our CMOs for our product and product candidates will need to be prepared to undergo pre- approval inspection in connection with our regulatory filings, and we cannot be certain that we will be able to adequately support them through such inspection nor that they will successfully pass any such inspection. **For example, in January 2025, we received the Response Letter from the FDA relating solely to observations during pre- approval inspection of a third- party manufacturing facility in connection with our tab- cel BLA. The FDA also placed a clinical hold on our INDs for tab- cel as well as our product candidate ATA3219. The clinical hold is directly linked to inadequately addressed GMP compliance issues identified during the pre- approval inspection of a third party manufacturing facility referenced in the Response Letter we received in January 2025.** To meet our projected supply needs for clinical and commercial materials to support our activities through regulatory approval and commercial manufacturing of tab- cel, product candidates resulting from our next- generation CAR T programs or any other product candidates, we will need to transition the manufacturing of these materials to a CMO. Regardless of where production occurs, we will need to develop relationships with suppliers of critical starting materials or reagents, increase the scale of production and demonstrate comparability **and / or non- inferiority** of the material produced at these facilities to the material that was previously produced. Transferring manufacturing processes, analytical methods and know- how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different

facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We would expect additional comparability work will also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know- how and data ~~has~~ **have** been adequately incorporated into the manufacturing process until the completion of studies (and the related evaluations) intended to demonstrate the comparability of material previously produced with that generated by us or our CMOs. If we or our CMOs are not able to successfully transfer and produce comparable product and product candidates, our ability to further develop and manufacture our product and product candidates may be negatively impacted. We still may need to identify additional CMOs for continued production of supply for some of our product and product candidates. Given the nature of our manufacturing processes, the number of CMOs who possess the requisite skill and capability to manufacture our T- cell immunotherapy product candidates, and the critical intermediates or reagents used to manufacture such products, are limited. We have not yet identified alternate suppliers in the event the current CMOs that we utilize are unable to scale production, or if we otherwise experience any problems with them. We rely on our CMOs and manufacturing network for the production of our product and product candidates. Our supply, and ability to maintain inventory, of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, failure to meet regulatory or cGMP requirements, labor or raw material shortages, public health epidemics, natural disasters, power failures, cyber- attacks and many other factors. If we encounter any manufacturing or supply chain difficulties, we may be unable to meet the demand for our products and product candidates. Manufacturing cellular therapies is complicated and tightly regulated by the FDA and comparable regulatory authorities around the world, and although alternative third party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers, transfer manufacturing procedures and analytical methods to these alternative suppliers, and demonstrate comparability **and / or non- inferiority** of material produced by such new suppliers. New manufacturers of any product, product candidate **,** or intermediate would be required to qualify **procedures** under applicable regulatory requirements. These manufacturers may not be able to manufacture our product and product candidates at costs, or in sufficient quantities, or in a timely manner necessary to complete development of our product candidates or make commercially successful products. If we are unable to arrange for alternative third party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. In addition, should the FDA or comparable regulatory authorities not agree with our product candidate specifications and comparability methodologies or assessments for these materials, regulatory authorities may require that we conduct additional studies, including bridging comparability testing, and further clinical development or commercial launch of our product candidates could be substantially delayed. Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured product and product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third party manufacturer does not maintain the financial resources to meet its obligations under the manufacturing agreement, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to manufacture our product candidates or any products we or our partners may eventually commercialize in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know- how, the possibility that the third party does not devote sufficient time or resources to our product candidates or any products we or our partners may eventually commercialize based on its own business priorities, the possibility that the third party is acquired by another party and changes its business priorities, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. For example, the CRL MSA ~~expires~~ **expired** on ~~March~~ **August** 31, 2024 **and** ~~. While~~ we are in ~~active~~ negotiations ~~with~~ **to wind- down our activities at** CRL **. We are exploring other options** for **the** ~~a new commercial manufacturing~~ **manufacture** ~~agreement~~ **of our product and product candidates** , there can be no assurance that we will be able to **find a new CMO or** enter into a new commercial drug product supply agreement with ~~CRL~~ **a new CMO** on terms favorable or acceptable to us or at all. Any delays in entering into a new commercial manufacturing agreement ~~and / or further extension of the current CRL MSA~~ could delay the development and commercialization of our product and product candidates, if approved ~~. In addition, if we are unable enter into a new commercial manufacturing agreement with CRL on acceptable terms, or at all, we would have to explore other options for the manufacture of our product and product candidates, which could harm our business~~ . If Fujifilm does not perform its obligations under the Fujifilm MSA adequately or does not devote sufficient time or resources to our product or product candidates, our operations, including the commercialization of our products, may be adversely impacted. Similarly, if CRL does not perform its obligations under the CRL MSA adequately or does not devote sufficient time or resources to our product or product candidates, our operations, including the commercialization of our products, may be adversely impacted. We also have non- cancellable minimum purchase commitments for products and services in certain ~~of our~~ agreements with our CMOs, if we do not fulfill such minimum purchase commitments, we will need to pay such CMOs the difference between the applicable minimum purchase commitment and our actual purchases of products and services for a given period. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we or our partners may eventually commercialize be manufactured according to cGMP, cGTP and similar regulatory jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have limited control over our manufacturers' compliance with these regulations and standards and although we monitor our manufacturers, we depend on them to provide honest and accurate information. Any failure by our third party manufacturers to comply with cGMP or cGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical studies, refusal to approve pending applications or supplemental applications, detention ~~or~~ **of** product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties. We depend on third party suppliers and testing laboratories for key materials used to produce or test our product and product candidates. Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate for an ongoing clinical study could considerably delay initiation or completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If raw materials or components cannot be purchased or fail to meet approved specifications, the commercial launch of our product and product candidates could be delayed, or there could be a shortage in supply, which could impair our ability to generate revenues from the sale of our product and product candidates. **In January 2025, we received the Response Letter from the FDA relating solely to observations during pre- approval inspection of a third- party manufacturing facility in connection with our tab- cel BLA. The FDA also placed a clinical hold on our INDs for tab- cel, as well as our product candidate ATA3219. The clinical hold is directly linked to inadequately addressed GMP compliance issues identified during the pre- approval inspection of a third party manufacturing facility referenced in the Response Letter. Although our ATA3219 product candidate is manufactured at a separate, fully compliant GMP- certified facility, the starting materials used in its production are affected by the compliance issues at the same third- party facility referenced in the Response Letter.** We are dependent on Pierre Fabre for the commercialization of tab- cel (Ebvallo in the ~~EU~~ **EEA** , **Switzerland and the** UK) worldwide, including the United States. The failure of Pierre Fabre to meet its contractual, regulatory or other obligations could adversely affect our business and our obligations under the HCRx Agreement. We have entered into the A & R Commercialization Agreement for tab- cel (Ebvallo in the ~~EU~~ **EEA, Switzerland** and the UK) worldwide for EBV- positive cancers and are in the process of negotiating amendments to certain ancillary agreements as contemplated by the A & R Commercialization Agreement to further advance our partnership with Pierre Fabre. The closing of the A & R Commercialization Agreement occurred in December 2023. As a result, we are entirely dependent on Pierre Fabre for marketing and commercialization, including negotiation of pricing and reimbursement, of tab- cel. The timing and amount of any milestone and royalty payments we may receive under the A & R Commercialization Agreement, as well as the commercial success of tab- cel, will depend on, among other things, the efforts, allocation of resources, negotiation of pricing and reimbursement and successful commercialization of tab- cel by Pierre Fabre. Under the terms of the A & R Commercialization Agreement, if we receive US BLA approval for tab- cel in patients with EBV PTLD, we are required to transfer the BLA to Pierre Fabre. Pierre Fabre will be responsible for obtaining all other regulatory approvals and maintaining all regulatory approvals. We will depend on Pierre Fabre to comply with numerous and varying regulatory requirements governing, if and when applicable, the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post- marketing information. We do not control the individual efforts of Pierre Fabre and have limited ability to terminate the A & R Commercialization Agreement if Pierre Fabre does not perform as expected. The failure of Pierre Fabre to devote sufficient time and effort to comply with regulatory requirements and maintain the US BLA (if approved), the ~~EU~~ **EEA, Switzerland** and UK marketing authorizations and other regulatory approvals and / or to meet their obligations to us, could have an adverse impact on our financial results and operations, and our obligations under the HCRx Agreement with respect to the Initial Territory **. Furthermore, we are responsible for manufacturing and supplying tab- cel to Pierre Fabre for commercialization in the Territory at cost plus a margin until the transfer of manufacturing responsibility to Pierre Fabre. Pierre Fabre will assume the responsibility and cost for the manufacture and supply of tab- cel in the Territory upon the Manufacturing Transition Date, which is defined as the earlier of i) the date on which all activities relating to the transfer of tab- cel manufacturing, pursuant to the A & R Commercialization Agreement, from Atara to Pierre Fabre have been completed to the reasonable satisfaction of both parties, or ii) December 31, 2025, throughout the remainder of the term of the A & R Commercialization Agreement. Pierre Fabre and we are to use commercially reasonable efforts to achieve this prior to the earlier transfer date from Atara to Pierre Fabre of the first marketing authorization in the Additional Territory or the first BLA. We are in active discussions with Pierre Fabre on accelerating the progressive transfer of all operational activities related to tab- cel, except the BLA sponsorship, to be completed as early as the end of the first quarter of 2025, as well as assumption by Pierre Fabre of certain costs related to the remediation of the third party manufacturing facility to address the FDA' s requests in order to lift the clinical hold and to support resubmission of the BLA for tab- cel. As part of these discussions, we expect to agree to reduce the amount of certain future potential regulatory and commercial milestone payments relating to tab- cel in the Additional Territory. Any delays in completing the manufacturing transfer to Pierre Fabre will increase our costs in order to meet our supply obligations and adversely impact our ability to develop our product candidates, and any reduction in amounts of future potential regulatory or commercial milestone payments may impact our future cash flows** . We also depend on Pierre Fabre to comply with all applicable laws relative to the commercialization of tab- cel in the Additional Territory. The failure of Pierre Fabre to devote sufficient time and effort to the commercialization of tab- cel; to meet their obligations to us, including for future royalty and milestone payments; to adequately deploy business continuity plans in the event of a crisis; and / or to satisfactorily resolve significant disagreements with us or address other factors could have an adverse impact on our financial results and operations. In addition, if Pierre Fabre violates, or are alleged to have violated, any laws or regulations during the performance of their obligations for us, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences. Any termination, breach or expiration of the A & R Commercialization Agreement or ancillary agreements, could have a material adverse effect on our financial position, and our obligations under the HCRx Agreement with

respect to the Initial Territory, by reducing or eliminating our right to receive fees, milestones and royalties. In such an event, we may be required to devote additional efforts and to incur additional costs associated with the transfer of regulatory approvals and commercialization of tab- cel. Alternatively, we may attempt to identify and transact with a new commercialization partner, but there can be no assurance that we would be able to identify a suitable partner or transact on terms similar to the A & R Commercialization Agreement or that are favorable to us. We may not realize the benefits of strategic alliances that we may form in the future or of potential future product acquisitions or licenses. We may desire to form additional strategic alliances, commercialization partnerships, create joint ventures or collaborations, enter into licensing arrangements with third parties or acquire products or business, in each case that we believe will complement or augment our existing business. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and transactions and the negotiation process is time- consuming and complex and there can be no assurance that we can enter into any of these transactions even if we desire to do so. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate a positive benefit / risk profile. Any delays in entering into new strategic alliances agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. In addition, any termination of established strategic alliance agreements will terminate any potential future funding we may receive under the relevant agreements, and we would have to seek a new partner for development or commercialization, curtail or abandon that development or commercialization, or undertake and fund the development and commercialization of the relevant product. If we seek a new partner but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of products ourselves, we would have to explore other strategic options, including curtailing or abandoning that development or commercialization, which could harm our business. ~~For example, effective July 31, 2022, we terminated the agreements with Bayer pursuant to the Termination, Amendment and Program Transfer Agreement (Bayer Termination Agreement).~~ If we license products or acquire businesses, we may not be able to realize the benefit of these transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following an acquisition or license, we will achieve the financial or strategic results that would justify the transaction. Risks Related to Our Intellectual Property If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected. We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements – both that we own or possess or that are owned or possessed by our partners ~~that~~ **and** are in- licensed to us – to protect the intellectual property related to our technology, product and product candidates. When we refer to " our " technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in- license, many of which are critical to our intellectual property protection and our business. For example, the product, product candidates and platform technology we have licensed from our partners are protected primarily by patent or patent applications of our partners that we have licensed and as confidential know- how and trade secrets. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have. The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U. S. Patent and Trademark Office (USPTO) and non- U. S. patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. We may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from ~~issuing~~ **being issued** as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our ~~product~~ **products** and product candidates in the U. S. or in other countries. Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product and product candidates, third parties may **still** challenge the validity, enforceability or scope thereof, which may result in these patents being narrowed, invalidated or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable. Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product and product candidates or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same effect as our product and product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product and product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product and product candidates are threatened, it could jeopardize our ability to commercialize our ~~product~~ **products** and product candidates and dissuade companies from collaborating with us. We may also desire to seek a license from a third party who owns intellectual property that may be useful for providing exclusivity for our product and product candidates, or for

providing the ability to develop and commercialize a product candidate in an unrestricted manner. There is no guarantee that we will be able to obtain a license from such a third party on commercially reasonable terms, or at all. **Additionally** ~~In addition~~, 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. 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. We and our partners have filed a number of patent applications ~~covering~~ **with claims directed to** our product and product candidates or methods of using or making **the product and** those product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of **claims in** any such patents that are ultimately issued or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Because patent applications in the U. S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our partners were the first to file any patent application related to a product or product candidate. We or our partners may also become involved in proceedings regarding our patents, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and inter partes and post- grant review proceedings before the USPTO the European Patent Office and other **foreign** ~~non- U. S.~~ patent offices. Even if granted, patents have a limited lifespan. In the U. S., the natural expiration of a patent generally occurs 20 years after it is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical studies or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product and product candidates under patent protection, if approved, could be reduced. Even if patents covering our product and product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products, as we may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates. Furthermore, the research resulting in certain of our licensed patent rights and technology was funded by the U. S. government. As a result, the government has certain rights to these patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non- exclusive license authorizing the government to practice the invention for or on behalf of the U. S. These rights may permit the government to disclose confidential information on which we rely to third parties and to exercise march- in rights to use or allow third parties to use our licensed technology. The government can exercise its march- in rights if it determines that action is necessary because we fail to achieve practical application of the government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U. S. industry. In addition, our rights in any inventions that result from government- funded research may be subject to certain requirements to manufacture products embodying these inventions in the U. S. If we are sued for infringing the intellectual property rights of third parties, the resulting litigation could be costly and time- consuming and could prevent or delay our or our partners' development and commercialization efforts. Our commercial success depends, in part, on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the U. S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and inter partes and post- grant review proceedings before the USPTO and non- U. S. patent offices. Numerous U. S. and non- U. S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product and product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product and product candidates may be subject to claims of infringement of third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. Third parties may assert infringement claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product and product candidates that we failed to identify. For example, patent applications covering our product and product candidates could have been filed by others without our knowledge, since these applications generally remain confidential for some period of time after their filing date. Even pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our product and product candidates or their use or manufacture. In addition, we may have analyzed patents or patent applications of third parties that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product and product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product, product candidates or our activities infringing their claims. If we or our partners are sued for patent infringement, we would need to demonstrate that our product candidates, ~~products~~ **product** and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. If any issued third **-** party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product or product candidate until the relevant patent expired. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product or product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all.

Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. We may face claims that we misappropriated the confidential information or trade secrets of a third party. If we are found to have misappropriated a third party' s trade secrets, we may be prevented from further using these trade secrets, which could limit our ability to develop our product candidates. Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product, product candidates, programs or intellectual property. In the event of a successful intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product and product candidates, which may be impossible or require substantial time and monetary expenditure. In addition to paying monetary damages, we may lose valuable intellectual property rights or personnel and the parties making claims against us may obtain injunctive or other equitable relief, which could impose limitations on the conduct of our business. We may also elect to enter into license agreements in order to settle patent infringement claims prior to litigation, and any of these license agreements may require us to pay royalties and other fees that could be significant. As a result of all of the foregoing, any actual or threatened intellectual property claim could prevent us or our partners from developing or commercializing a product or product candidate or force us to cease some aspect of our business operations. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on all of our ~~product~~ **products** and product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in certain countries outside the U. S. may be less extensive than those in the U. S. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the U. S. Consequently, we and our partners may not be able to prevent third parties from practicing our inventions in countries outside the U. S., or from selling or importing infringing products made using our inventions in and into the U. S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise- infringing products to territories where we and our partners have patent protection but where enforcement is not as strong as that in the U. S. These infringing products may compete with our product and product candidates in jurisdictions where we or our partners have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so 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 and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our partners to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our partners. We or our partners may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful. We have in- licensed a significant portion of our intellectual property from our partners. If we breach any of our license agreements with these partners, we could lose the ability to continue the development and potential commercialization of one or more of our product candidates. We hold rights under license agreements with our partners, including MSK ~~and QIMR Berghofer~~ that are important to our business. Our discovery and development platform is built, in part, around patent rights in- licensed from our partners. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales. If there is any conflict, dispute, disagreement or issue of nonperformance between us and our counterparties regarding our rights or obligations under these license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations, we may be liable to pay damages and our counterparties may have a right to terminate the affected license **. For example, we are in disagreement with MSK on whether we owe a portion of the upfront payments and milestones we received from Pierre Fabre under the A & R Commercialization Agreement to MSK under the terms of our license agreements with MSK. We have entered into evaluative non- binding mediation with MSK to potentially resolve this disagreement. There is no guarantee we will reach a favorable outcome in the mediation or on this matter and we may owe a portion of future milestones we receive from Pierre Fabre to MSK** . The termination of any license agreement with one of our partners would materially adversely affect our ability to utilize the intellectual property that is subject to that license agreement in our drug discovery and development efforts, our ability to enter into future collaboration, licensing and / or marketing agreements for one or more affected product and product candidates and our, or our partners' ability to commercialize the affected product and product candidates. Furthermore, a disagreement under any of these license agreements may harm our relationship with the partner, which could have negative impacts on other aspects of our business. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time- consuming and unsuccessful and have a material adverse effect on the success of our business. Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the

future, we or our partners may elect to initiate legal proceedings to enforce or defend our or our partners' intellectual property rights, to protect our or our partners' trade secrets or to determine the validity or scope of our intellectual property rights. Any claims that we or our partners assert against perceived infringers could also provoke these parties to assert counterclaims against us or our partners alleging that we or our partners infringe their intellectual property rights or that our intellectual property rights are invalid. Interference or derivation proceedings provoked by third parties, brought by us or our partners, or brought by the USPTO or any non- U. S. patent authority may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our partners may also become involved in other proceedings, such as reexamination or opposition proceedings, inter partes review, post- grant review or other pre- issuance or post- grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any of these proceedings could require us or our partners to cease using the related technology and commercializing our product and product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our partners a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product and product candidates. Any intellectual property proceedings can be expensive and time- consuming. Our or our partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our partners can. Accordingly, despite our or our partners' efforts, we or our partners may not be able to prevent third parties from infringing upon or misappropriating our intellectual property rights, particularly in countries where the laws may not protect our rights as fully as in the U. S. Even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected and our business could be harmed. In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. The T- cell immunotherapy product candidates and platform technology we have licensed from our partners are protected primarily as confidential know- how and trade secrets. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market. Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, CMOs, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the U. S. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition. Risks Related to Commercialization of Our Product and Product Candidates Our commercial success depends upon **developing a clearly differentiated product and** attaining significant market acceptance of our product and product candidates, if approved, among physicians, patients, healthcare payors and the medical community, including hospitals and outpatient clinics. Even if we or our partners obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics. Market acceptance of any of our product and product candidates for which we receive approval depends on a number of factors, including: • the efficacy and safety of the product candidates as demonstrated in clinical studies; • the clinical indications and patient populations for which the product candidate is approved; • the inclusion into clinical treatment guidelines; • acceptance by physicians and patients of the drug as a safe and effective treatment; • the administrative and logistical burden of treating patients **; • the differentiation profile versus other approved therapies at the time of commercialization** ; • the ability to identify in a timely manner the appropriate patients who will benefit from specific therapy;

• the consideration of novel cellular therapies by physicians, hospitals and third party payors; • the potential and perceived advantages of product candidates over alternative treatments; • the safety of product candidates seen in a broader patient group, including its use outside the approved indications; • any restrictions on use together with other medications; • the prevalence and severity of any side effects; • product labeling or product insert requirements of the FDA or other regulatory authorities; • the **geography and** timing of market introduction of our products as well as competitive products; • the development of manufacturing and distribution processes for our product and product candidates; • the cost of treatment in relation to alternative treatments; • the availability of coverage and adequate reimbursement from, and our commercialization partners ~~'~~ ability to negotiate pricing with, third- party payors and government authorities **; • the limited healthcare resources to accommodate CAR T therapies** ; • relative convenience and ease of administration; • the ability to achieve a pricing and reimbursement recommendation or commercial agreement with national payors; and • the effectiveness of our commercialization partners ~~'~~ sales and marketing efforts. Even if we or our partners are able to commercialize our product and product candidates, the products may not receive coverage and adequate reimbursement from third party payors in the U. S. and in other countries in which our partners seek to commercialize our products, which could harm our business. Our ability to commercialize any product successfully 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. Government authorities and third party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Government authorities and third party payors continue to support initiatives to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, 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. Third party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. In some countries such as the U. S., greater cost- shifting from the payor to the patient is also a trend, and higher patient copayments or other administrative burdens could lead to reduced demand from patients or healthcare professionals. This could particularly be the case in a challenging economic climate. Coverage and reimbursement may impact the demand for, or the price of, any product or product candidate for which we obtain regulatory approval, and ultimately our partners' ability to successfully commercialize any product or product candidate for which we obtain regulatory 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 comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. 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 U. S. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third party payors in the U. S. Third party payors in the U. S. often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. The process of determining coverage and reimbursement is often time consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third party payors will decide with respect to coverage and reimbursement for our drug products. Our partners' inability to promptly obtain coverage and ~~profitable~~ **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 and our overall financial condition. Current and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of our product candidates and affect the prices for our product and product candidates. The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the U. S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post- approval activities and affect our ability to successfully sell any product and product candidates for which we obtain regulatory approval. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act (ACA), was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U. S. pharmaceutical industry. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, **and** provided incentives to programs that increase the federal government' s comparative effectiveness research **. As of January 1, 2024, manufacturers' Medicaid Drug Rebate Program rebate liability is no longer capped,**

potentially resulting in a manufacturer paying more in Medicaid Drug Rebate Program rebates than it receives on the sale of certain covered outpatient drugs . Other legislative changes have been proposed and adopted in the U. S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by the U. S. Congress. This includes aggregate reductions of Medicare payments to providers of 2 % per fiscal year, which went into effect in April 2013. As a result of the COVID- 19 pandemic, this reduction was temporarily suspended from May 1, 2020 through March 31, 2022, with subsequent reductions to 1 % from April 1, 2022 ~~until~~ **through** June 30, 2022. The 2 % reduction was then reinstated and has been in effect since ~~June 30~~ **July 1** , 2022, and will remain in effect **through** ~~(with additional reductions of 2. 25 % in~~ the first ~~half of~~ **eight months in which the FY** ~~2030~~ **2032 sequestration order** ~~and 3 % in the second half of 2030 to offset the COVID- 19 suspension) until 2031 unless additional Congressional action~~ is ~~taken~~ **in effect** . In January 2013, the American Taxpayer Relief Act of 2012 was enacted which, among other things, further reduced Medicare payments to several providers, including hospitals and outpatient clinics, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. There have been judicial and Congressional challenges to numerous elements of the ACA, as well as efforts by both the executive and legislative branches of the federal government to repeal or replace certain aspects of the ACA. While the U. S. Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties, starting January 1, 2019, for not complying with the ACA' s individual mandate to carry health insurance and eliminating the implementation of certain mandated fees. On June 17, 2021, the U. S. Supreme Court dismissed a legal challenge to the law brought by several states arguing that, without the individual mandate, the entire ACA was unconstitutional. The Supreme Court dismissed the lawsuit without ruling on the merits of the states' constitutionality arguments. Further, the **Inflation Reduction Act (** IRA **)** , signed into law in August 2022, extended the provision of enhanced subsidies for individuals purchasing health coverage through the ACA marketplace. The enhanced subsidies, which were originally passed as part of the American Rescue Plan Act are now extended through 2025. In the future, there may be additional challenges and / or amendments to the ACA. It is unclear how future litigation and the healthcare reform measures of ~~the Biden~~ **future presidential** ~~administration~~ **administrations** will impact the ACA and our business. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare, including by imposing price controls, may adversely affect the demand for our product and product candidates for which we obtain regulatory approval and our ability to set a price that we believe is fair for our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. For example, in April 2023, the European Commission adopted a wide- ranging proposal for a new Directive and a new Regulation. If made into law, this proposal will revise and replace the existing general pharmaceutical legislation. This change will likely result in significant changes to the pharmaceutical industry. In particular, it is expected that the new Directive and Regulations will, if made into law, affect the duration of the period of regulatory protection afforded to medicinal products including regulatory data protection (also called " data exclusivity "), marketing exclusivity afforded to orphan medicinal products, as well as the conditions of eligibility to the orphan designation. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the U. S. or foreign regulations, guidance or interpretations will be changed, or what the impact of these changes on the regulatory approvals of our product and product candidates, if any, may be. In the U. S., the EU and other potentially significant markets for our product and product candidates, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices for certain products in certain markets. In the U. S., there have been several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Consolidated Appropriations Act of 2021 included several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of Health and Human Services, Labor, and the Treasury. Additionally, the IRA allows Medicare to: beginning in 2026, establish a " maximum fair price " for certain pharmaceutical and biological products covered under Medicare Parts B and D; beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation; and beginning in 2025 impose new discount obligations on pharmaceutical and biological manufacturers for products covered under Medicare Part D. CMS ~~has also~~ **continues to** ~~taken~~ **take** steps to implement the IRA, including **, most notably** : ~~on June 30~~ **releasing the negotiated maximum prices** , **which will be effective in** ~~2023~~ **2026** , **for** ~~issuing guidance detailing the requirements and parameters of~~ the first ~~round of price negotiations, to take place during 2023 and 2024, for products subject to the " maximum fair price " provision that would become effective in 2026; on August 29, 2023, releasing the initial list of~~ ten drugs **that were** subject to ~~price~~ **the IRA' s** ~~negotiations~~ **negotiation process** ~~; on November 17, 2023~~ , releasing **quarterly** ~~guidance outlining the methodology for identifying certain manufacturers eligible to participate in a phase- in period where discounts on applicable products will be lower than those required by the Medicare Part D Manufacturer Discount Program; and on December 14, 2023, releasing a list~~ **lists** of ~~48~~ Medicare Part B products that ~~had an~~ **are subject to** adjusted coinsurance ~~rate~~ **rates** based on the inflationary rebate provisions of the IRA ~~for the time period of January 1~~ , **and announcing a list of fifteen additional drugs that will be subject to price negotiations during** ~~2024~~ **2025** ~~to March 31, 2024~~ . While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical

manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U. S. Department of Health and Human Services, the Secretary of the U. S. Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA' s drug price negotiation provisions. There have also been administrative developments in the U. S. related to drug pricing. For example, on ~~February 2~~ **June 27** , ~~2022~~ **2023** , the **Center for Medicare Innovation at CMS** ~~Biden Administration signaled its continued commitment to the Cancer Moonshot initiative, which was initially launched in 2016. In its announcement~~ **announced a new model** , the ~~administration noted~~ **Enhancing Oncology Model,** that ~~its~~ **is designed** ~~new goals under the initiative include addressing inequities in order~~ to **make** ~~ensure broader access to cutting- edge cancer therapeutics and investing in a robust pipeline for new treatments. On September 12, 2022, President Biden issued an Executive Order to promote biotechnology and biomanufacturing innovation. The Order noted several methods through which the Biden Administration would support the advancement of biotechnology and biomanufacturing in healthcare, and instructed the Department of Health and Human Service to submit, within 180 days of the Order, a report assessing how to use biotechnology and biomanufacturing to achieve medical breakthroughs, reduce the overall burden of disease, and improve health outcomes. On October 14, 2022 President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of the Department of Health and Human Services to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. The Executive Order further directed the Secretary of the Department of Health and Human Services to submit, within 90 days of the date of the Executive Order, a report regarding any models that may lead to lower cost- sharing for commonly used drugs and support value- based payment that promotes~~ high- quality **cancer** care **more affordable to both patients and Medicare** . **Additionally** ~~Most recently~~ , on February 14, 2023, the Department of Health and Human Services issued a report ~~in response to the October 14, 2022 Executive Order,~~ which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a " high- value drug list " setting the maximum ~~co~~ **out** ~~- payment amount~~ **of- pocket costs** for certain common generic drugs at $ 2 **per month per drug** ; (2) a Medicaid- focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi- state outcomes- based agreements for certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments. ~~On August 29, 2023, CMS released an initial list of ten drugs subject to price negotiations. This negotiation process will occur during 2023 and 2024 and result in maximum prices that will be effective beginning in 2026. While it remains to be seen how the drug pricing provisions imposed by the Inflation Reduction Act (IRA) will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U. S. Department of Health and Human Services, the Secretary of the U. S. Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA' s drug price negotiation provisions.~~ Other ~~proposed~~ **recent** administrative actions may affect our **upcoming** government pricing responsibilities **stemming from our anticipated participation in government pricing programs** . For example, **in September 2024,** CMS ~~has issued proposals~~ **published a final rule that included significant revisions** to **certain** ~~amend the existing~~ Medicaid Drug Rebate Program ~~regulations~~ **provisions, including, but not limited to: (i) new definitions for key terms under the Medicaid Drug Rebate Program, such as" covered outpatient drug" and" market date"; (ii) revised processes for identifying drug misclassifications, as well as additional penalties that can be imposed against manufacturers in connection with such misclassifications; and (iii) a new 12- quarter time limit for manufacturers to initiate disputes, hearing requests, and audits for state- invoiced rebate amounts** . In addition, there are pending legal and legislative developments relating to the 340B drug pricing program, including ongoing litigation challenging federal enforcement actions against manufacturers and recently introduced and enacted state legislation. **In March 2024, the US Court of Appeals for the Eighth Circuit upheld the Arkansas law prohibiting drug makers for restricting 340B drug discounts for providers using contract pharmacies.** It remains to be seen how these drug pricing initiatives will affect the broader pharmaceutical industry **. The results of the 2024 Presidential and Congressional elections, and potential subsequent developments further increase the uncertainty related to the healthcare regulatory environment, particularly given the Trump Administration' s stated commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS and CMS. In addition, on June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) " must exercise their independent judgment " and " may not defer to an agency interpretation of the law simply because a statute is ambiguous. " The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by CMS and other agencies with significant oversight of the healthcare industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies may be subject to increased litigation and judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts that are difficult to predict but could have a material adverse effect on our business and financial condition. For example, certain of these changes could impose additional limitations on the rates we will be able to charge for our future products or the amounts of reimbursement available for our future products from governmental agencies or third- party payors** . At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries

and bulk purchasing. Another emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be " high- cost ". Furthermore, the increased emphasis on managed healthcare in the U. S. and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales. These pressures can arise from rules and practices of managed care groups, other insurers, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. In addition, there is significant uncertainty regarding the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost- effectiveness of our product and product candidates. If third party payors do not consider our product and product candidates to be cost- effective compared to other therapies, the payors may not cover our product and product candidates after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis. Price controls may be imposed in foreign markets, which may adversely affect our future profitability. In some countries, particularly Member States of the EU and the UK, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low- priced and high- priced Member States, can further reduce prices. In some countries, we, or our collaborators, may be required to conduct a clinical study or other studies that compare the cost- effectiveness of our product and product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product and product candidates. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, **patient convenient,** have fewer side effects or are less expensive than any products that we may develop **, and if our product cannot be administered in a treatment setting proximate to the patient (e. g., community practices)** . Additionally, our commercial opportunities will be reduced or eliminated if novel upstream products or changes in treatment protocols reduce the overall incidence or prevalence of our current or future target diseases. Competition could result in reduced sales and pricing pressure on our product and product candidates, if approved by applicable regulatory authorities. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product and product candidates. There are currently no FDA- approved products for the treatment **relapse and / or refractory** of EBV PTLD, and there are no EC- approved products for this indication except for Ebvallo. However, we are aware some marketed products and therapies are used per global physician treatment guidelines in the US and the EU in the treatment of EBV PTLD by some healthcare professionals and institutions, such as rituximab and combination chemotherapy regimens. ~~In addition, a number of companies and academic institutions are developing product candidates for EBV PTLD and other EBV- driven diseases, for example, Viracta Therapeutics, Inc., which is conducting a pivotal, Phase 2 clinical study for nanatinostat (formerly named tractinostat, or VRx- 3996) in combination with antiviral drug valganciclovir in relapsed / refractory EBV lymphomas.~~ There are currently ~~six~~ **seven** autologous CAR T therapies approved in the U. S. and / or EU: Novartis' Kymriah ® (tisagenlecleucel), Gilead / Kite' s Yescarta ® (axicabtagene ciloleucel) and TecartusTM (brexucabtagene autoleucel) and Bristol- Myers Squibb' s Breyanzi ® (lisocabtagene maraleucel) and Abecma (idecabtagene vicleucel) with 2seventy bio, Johnson & Johnson and Legend Biotech' s CarvyktiTM (ciltacabtagene autoleucel). There are many CAR- mediated cell therapies in development, and, although the majority are autologous, they also include allogeneic and off- the- shelf cell therapies. There are multiple allogeneic CAR platforms being developed with differences in approaches to minimize instances of donor cells recognizing the patient' s body as foreign or rejection of the donor cells by the patient' s body. These approaches include the use of gene- editing to remove or inhibit the TCR and the use of cell types without a TCR. The majority of clinical stage allogeneic CAR programs utilize alpha beta T cells as the cell type and gene editing of the T- cell receptor and HLA as the preferred technology approach, however, other strategies are also in development such as Gamma Delta T cells and NK cells. It is possible that some of these other approaches will have more favorable characteristics than the approach we utilize, which would result in them being favored by potential partners or customers over our products. Depending on the diseases (such as autoimmune diseases) that we target in the future, we may face competition from both autologous and allogeneic CAR therapies and other modalities (e. g., small molecules, antibodies, bispecifics) in the indication of interest. Many of the approved or commonly used drugs and therapies for our current or future target diseases, including EBV PTLD **NHL** and ~~MS~~ **Lupus** , are well established and are widely accepted by physicians, patients and third party payors. Some of these drugs are branded and subject to patent protection, and other drugs and nutritional supplements are available on a generic basis. Insurers and other third party payors may encourage the use of generic products or specific branded products. We expect that our product and our product candidates, if approved, will be priced at a significant premium over competitive generic products. Absent differentiated and compelling clinical evidence, pricing premiums may impede the adoption of our products over currently approved or commonly used therapies, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our ~~products~~ **product candidates** continue in

clinical development. Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early- stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies or if they are acquired by larger companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies, establishing agreements with CROs and CMOs, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover development and other expenses. We are subject to certain contractual obligations under our royalty financing agreement with HealthCare Royalty Partners and may be subject to claims for damages if we fail to fulfill these obligations. In December 2022, we entered into a purchase and sale agreement (the HCRx Agreement) with HCR Molag Fund, L. P. (HCRx). Under the terms of the HCRx Agreement, we received $ 31. 0 million in cash in consideration for our right to receive a portion of future royalty payments and certain milestones for Ebvallo in the Initial Territory due to us from Pierre Fabre under the A & R Commercialization Agreement. The HCRx Agreement contains certain customary terms and conditions, including representations and warranties, covenants, and indemnification obligations in favor of each party. Among these terms, there are certain covenants regarding our compliance with the A & R Commercialization Agreement. In the event of actual or alleged breaches of the A & R Commercialization Agreement or the HCRx Agreement, we could be subject to claims for damages from HCRx and could be subject to costly litigation. We expect the product candidates we develop will be regulated as biological products (biologics) and therefore they may be subject to competition sooner than anticipated. The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act 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 " interchangeable " based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products. We believe that our product and any of the product candidates we develop that are approved in the U. S. 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 generic 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 is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products. If we are unable to enter into agreements with third parties to market and sell our product and product candidates, we may be unable to generate any revenue from the sale of our products. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must enter into agreements with third parties to market and sell our product. There is no guarantee that we will be able to enter into such agreements with third parties or to do so on commercially reasonable terms or in a timely manner. Any failure or delay in entering into agreements with third parties to market and sell our products, would adversely impact the commercialization of these products. There can be no assurance that we would be able to identify a suitable third party to market and sell our product or agree upon terms with third parties that are favorable or acceptable to us, or at all. If we are unable to identify and reach agreement with a third party to market and commercialize our product, we may need to explore other strategic options, including commercializing products ourselves, and there is no guarantee we can successfully commercialize products ourselves. We may be competing with many companies that currently have extensive and well- funded sales and marketing operations. Without a sufficiently scaled, appropriately timed and trained third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies. We may encounter difficulties in managing our growth, including with respect to our employee base, and managing our operations successfully. As of December 31, ~~2023~~ **2024**, we had ~~225~~ **153** employees ~~, excluding those impacted by the reduction in force announced in November 2023. In January 2024, we announced another reduction of our workforce by approximately 25 %~~. We may encounter difficulties in managing the size of our operations to support our continuing development activities and the commercialization of our product and potential commercialization of our product candidates by our partners. As our development and commercialization plans and strategies continue to evolve, or as a result of any future acquisitions, we must continue to improve our managerial, operational, financial and other procedures and processes to manage the size our of operations. Our management, personnel and systems currently in place may not be adequate to support any future growth. Future growth would impose significant added responsibilities on members of management, including: • managing our

~~preclinical and~~ clinical studies effectively; • managing CMC operations and our external manufacturing partners effectively; • identifying, recruiting, maintaining, motivating and integrating additional employees, including the additional personnel needed to support continued development and of our product candidates; • managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; • improving our managerial, development, operational, information technology, and finance systems; and • expanding our facilities. As our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and ~~preclinical and~~ clinical studies effectively and hire, train and integrate additional management, research and development, regulatory, manufacturing and administrative personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company. Risks Related to Ownership of Our Common Stock Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance. Our stock price has fluctuated in the past and can be expected to be volatile in the future. **On June 20, 2024, we effected a 1- for- 25 reverse stock split of our common stock, which contributed to the fluctuation in our stock price.** From January 1, ~~2022~~ **2023** through December 31, ~~2023~~ **2024** , the reported sale price of our common stock has fluctuated between $ ~~0~~ **4** . ~~20~~ **97** and $ ~~16~~ **141** . ~~93~~ **00** per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies ~~. In particular, during the COVID- 19 pandemic the volatility of the stock market for biopharmaceutical companies was heightened~~ . As a result of the general volatility of the biopharmaceutical market, investors may experience losses on their investment in our common stock. The market price of our common stock may be influenced by many factors, including the following: • the success of competitive products or technologies; • regulatory actions with respect to our product candidates or products or our competitors' product candidates or products; • actual or anticipated changes in our growth rate relative to our competitors; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; • announcements of the results, including safety and efficacy of our product candidates, or progress of our clinical studies; • results of clinical studies, including safety and efficacy, of our product candidates or those of our competitors; • regulatory or legal developments in the U. S. and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any of our product candidates or clinical development programs; • the results of our efforts to in- license or acquire additional product candidates or products; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be similar to us; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • inconsistent or unusual trading volume levels of our shares or derivatives thereof; • announcement or expectation of additional financing efforts; • sales of our common stock by us, our insiders or our other stockholders; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; • general economic, industry and market conditions; and • the other risks described in this " Risk Factors " section. In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies, which has resulted in decreased stock prices for many companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of significant changes in U. S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and healthcare spending and delivery, including the possible repeal and / or replacement of all or portions of the Affordable Care Act or changes in tariffs and other restrictions on free trade stemming from U. S. and foreign government policies, or for other reasons, the financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. These market fluctuations may adversely affect the trading price of our common stock. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and divert management' s attention and resources, which could result in delays of our clinical studies or our partners' commercialization efforts. Our principal stockholders own a significant percentage of our stock and will be able to exert significant control or significant influence over matters subject to stockholder approval. Our principal stockholders own a significant portion of our outstanding common stock. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock. The interests of our significant stockholders may not always coincide with the interests of other stockholders **,** and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, ~~and~~ **which** might affect the market price for our common stock. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, 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. Moreover, certain holders of shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We have incurred and will continue to incur increased costs as a result of being a public company and

our management expects to devote substantial time to public company compliance programs. As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes- Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Stock Market to implement provisions of the Sarbanes- Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted and will adopt additional rules and regulations, such as mandatory " say on pay " voting requirements, that now apply to us. Stockholder activism, the current political environment and the potential for future regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and make some activities more time- consuming and costly. To the extent these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of potential gain for our stockholders. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock in one or more transactions at prices and in a manner we determine from time to time. These future issuances of common stock or common stock- related securities, together with the exercise of outstanding options or warrants, and any additional shares issued in connection with acquisitions or in- licenses, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock. To the extent equity valuations, including the trading price of our common stock, are depressed as a result of economic disruptions or other factors, the potential magnitude of this dilution will increase. Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity- based incentive awards to our employees, non- employee directors and consultants. Future grants of RSUs, options and other equity awards and issuances of common stock under our equity incentive plans will result in dilution and may have an adverse effect on the market price of our common stock. Some terms of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation (Certificate of Incorporation) and amended and restated bylaws (Bylaws), as well as Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include terms that: • permit our board of directors to issue up to 20, 000, 000 shares of preferred stock, with any rights, preferences and privileges as they may designate; • provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; • establish that our board of directors is divided into three classes, with each class serving three- year staggered terms, which makes it more difficult to replace a majority of our directors in a short period of time; • require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent; • provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder' s notice; • not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and • provide that special meetings of our stockholders may be called only by our board of directors, the chairperson of our board of directors or our chief executive officer. Any of the factors listed above may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any term of our Certificate of Incorporation or Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. Our Bylaws designate a state or federal court located within the State of Delaware as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our current or former directors, officers, stockholders, or other employees. Our bylaws provide that, unless we consent in writing to the selection of an

alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us under Delaware law, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, or other employee of the Company to us or our stockholders, (iii) any action asserting a claim against us or any of our directors, officers, or other employees arising pursuant to any provision of the DGCL or our Certificate of Incorporation or Bylaws (as either may be amended from time to time), (iv) any action asserting a claim against us governed by the internal affairs doctrine, or (v) any other action asserting an " internal corporate claim, " as defined under Section 115 of the DGCL. The forgoing provisions do not apply to any claims arising under the Securities Act and, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our current or former directors, officers, or other employees, which may discourage lawsuits with respect to such claims. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find the choice of forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. We ~~recently qualified~~ **qualify** as a " smaller reporting company " and a " non- accelerated filer, " and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to such companies could make our common shares less attractive to investors. As a result of our public float (the market value of our common shares held by non- affiliates) as of June 30, 2023, we qualify as a " smaller reporting company, " as defined under the Exchange Act. In addition, we are a " non- accelerated filer " as defined under the Exchange Act. For as long as we continue to be a smaller reporting company or a non- accelerated filer, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies or non- accelerated filers, as applicable, including, but not limited to, an exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404 of the Sarbanes- Oxley Act. If we choose to rely on any of these reporting and disclosure exemptions, the information we provide stockholders will be different than the information that is available with respect to many other public companies. Moreover, if some investors find our common stock less attractive as a result of any choices to reduce future disclosure or ~~have~~ **not having** an independent review and attestation of our internal control over financial reporting, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us and our business. In the event securities or industry analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. General Risk Factors Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel. We are highly dependent upon our executive officers and other key employees and the loss of the services of any of our executive officers or other key employees, including scientific, technical or management personnel, could impede the achievement of our corporate objectives. In August 2022, we announced a reduction of our workforce by approximately 20 % across all areas of our company, including members of management. In November 2023, we implemented a further reduction of our workforce by approximately 30 %, and in January 2024, we ~~announced~~ **conducted** an additional reduction of our workforce by approximately 25 %, including a member of management. **In September 2024, Pascal Touchon, our President and Chief Executive Officer stepped down from his position and was appointed Chairperson of our board of directors, and AnhCo " Cokey " Nguyen, our Chief Scientific and Technical Officer, was appointed as our President and Chief Executive Officer.** Losing members of management and other key personnel subjects us to a number of risks, including the failure to coordinate responsibilities and tasks, the necessity to create new management systems and processes, the impact on corporate culture, and the retention of historical knowledge **. In addition, we may not be able to effectively transition members of our management, including transitioning Dr. Nguyen into the position of President and Chief Executive Officer** . Our success depends on our ability to recruit, retain, manage and motivate our employees. Although we enter into employment agreements or offer letters with our employees, these documents provide for " at- will " employment, which means that any of our employees could leave our employment at any time, with or without notice. Competition for skilled personnel in our industry and geographic regions is intense and may limit our ability to hire and retain qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity awards that vest over time. The value to employees of equity awards may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Our relationships with customers and third party payors will be subject to applicable anti- kickback, fraud and abuse, privacy and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, including physicians, and third party payors will play a primary role in the recommendation and prescription of our product and any product candidates for which we obtain regulatory approval. Our current and future arrangements with third party payors and customers may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would market, sell and distribute our products. As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to

Medicare, Medicaid or other third party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If we obtain FDA approval of any of our product candidates and our partners begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs, distribution agreements, discounting, commission compensation, certain patient support offerings, and other business arrangements generally. In addition, the approval and commercialization of our product and any of our product candidates outside the United States will also likely subject us to foreign equivalents of ~~the~~ **such** healthcare laws ~~mentioned here~~ , among other foreign laws. ~~Restrictions under~~ **See Part I, Item 1, " Government Regulation and Product Approval – U. S. Health Care Laws " for additional details on** applicable federal and state healthcare laws and regulations that may affect ~~certain~~ **our** business **operations** ~~arrangements and our ability to operate include, but are not limited to, the following: • the federal healthcare Anti- Kickback Statute, a criminal law that governs, for example, our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • the FDCA and PHSA, which prohibit the misbranding and adulteration of biological products that are regulated as drugs, and which regulate the marketing of biological products; • federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • provisions enacted under the federal HIPAA impose criminal and civil liability for knowingly and willfully executing or attempting to execute, a scheme or artifice to defraud any healthcare benefit program and also impose criminal liability for, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services; • HIPAA, as amended by HITECH also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates and their subcontractors that use, disclose or otherwise process individually identifiable health information; • the federal Physician Payments Sunshine Act, implemented as the Open Payments Program, which requires certain manufacturers of drugs, devices, biologies and medical supplies to report annually to CMS information related to payments and other transfers of value to U. S.- licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives and U. S. teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; • state and foreign laws and regulations that are analogous to, and may be broader in scope than, the federal laws and regulations described in this risk factor, such as state anti-kickback and false claims laws, may apply to sales or marketing or other arrangements and claims involving healthcare items or services reimbursed by non- governmental third party payors, including private insurers; and • state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; some state laws require drug manufacturers to report information regarding pricing and marketing information related to payments and other transfers of value to physicians and other healthcare providers as well as those that require the registration of pharmaceutical sales representatives; and some other state laws require the protection of the privacy and security of health information, which may differ from each other in significant ways and often are not preempted by HIPAA~~ . Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement, and the curtailment or restructuring of our operations, reputational harm, contractual damages, and diminished profits and future earnings, any of which could adversely affect our ability to operate our business and our results of operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government- funded healthcare programs. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We are exposed to the risk of employee fraud or other misconduct, including 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 we have established, 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 studies, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and

prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical studies and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical studies, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or products that we may develop; • clinical holds or termination of clinical study sites or entire study programs; • injury to our reputation and significant negative media attention; • withdrawal of clinical study participants; • significant costs to defend the related litigation; • substantial monetary awards to study subjects or patients; • loss of revenue; • diversion of management and scientific resources from our business operations; and • the inability to commercialize any products that we may develop. We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. 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. As deemed necessary, we may expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. If we and our third party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We and our third party manufacturers are 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our or our third party manufacturers' use of 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. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials with a policy limit that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, 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 connection with our storage or disposal of biological or hazardous materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could adversely affect our business, financial condition, results of operations and prospects. The actual or perceived failure by us, our customers, or vendors to comply with increasingly stringent laws, regulations and contractual obligations relating to privacy, data protection, and data security could harm our reputation, and subject us to significant fines and liability. We are or may become subject to numerous domestic and foreign laws and regulations regarding privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations and may be inconsistent among countries, or conflict with other rules. We are also subject to the terms of our contractual obligations to customers and third parties related to privacy, data protection, and data security. The actual or perceived failure by us, our customers, our vendors, or other relevant third parties to address or comply with these laws, regulations, and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, cause regulators to reject, limit or disrupt our clinical trial activities, result in reputational harm, lead to a loss of customers, reduce the use of our products, result in litigation and liability, and could otherwise cause a material adverse effect on our business, financial condition, and results of operations. For example, the EU General Data Protection Regulation (EU) 2016 / 679 (EU GDPR) imposes strict requirements on in- scope organizations regarding the processing of personal information (i. e., data which identifies an individual or from which an individual is identifiable) of individuals (or data subjects). The EU GDPR governs the collection, use, disclosure, transfer and other processing of personal information and has direct effect in all EU Member States and extraterritorial effect where organizations outside of the European Economic Area (EEA) process personal information of individuals in the EEA in relation to the offering of goods or services to those individuals or the monitoring of their behavior. The UK has implemented the EU GDPR into its national law by virtue of section 3 of the European Union (Withdrawal) Act as the UK GDPR (together, the UK GDPR and the EU GDPR, the GDPR). Under the UK GDPR, companies established in the UK and companies not established in the UK but who process personal information of individuals in the UK in relation to the offering of goods or services to those individuals, or to the monitoring of their behavior will be subject to the UK GDPR. As such, the GDPR applies to us to the extent we are established in an EU Member State or the UK, we are processing personal information in the context of an establishment in an EU Member State or the UK or we are processing personal information in relation to the offering of goods or services to

individuals in the EEA or the UK or monitoring their behavior. The GDPR imposes onerous and comprehensive privacy, data protection, and data security obligations onto controllers, including, as applicable: (i) contractual privacy, data protection, and data security commitments, including the requirement to implement appropriate technical and organizational measures to safeguard personal information processed; (ii) establishing means for individuals to exercise their data protection rights (e. g., the right to erasure of personal information); (iii) limitations on retention and the amount of personal information processed; (iv) additional requirements pertaining to sensitive information (such as health data); (v) data breach notification requirements to: (x) supervisory authorities without undue delay (and no later than 72 hours where feasible) after becoming aware of the breach, unless the breach is unlikely to result in a risk to the data subjects' rights and freedoms; and / or (y) concerned individuals where the breach is likely to result in a high risk to their rights and freedoms; (vi) requirements to process personal information lawfully including specific requirements for obtaining valid consent from data subjects where consent is the lawful basis for processing; (vii) obligations to consider data protection as any new products or services are developed and designed; and (viii) accountability and transparency requirements, which require controllers to demonstrate and record compliance with the GDPR and to provide more detailed information to data subjects (such as clinical trial subjects and investigators) regarding processing. The GDPR also provides that EU Member States and the UK (as applicable) may introduce further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share personal information subject to the GDPR, cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition. In addition, the EU GDPR also prohibits the transfer of personal information from the EEA to countries that the European Commission does not recognize as having an " adequate " level of data protection unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information **(e. g., EU Standard Contractual Clauses or EU SCCs)** . Data protection laws in the UK (as discussed below) and Switzerland impose similar restrictions. **There** ~~One of the primary safeguards allowing U. S. companies to import personal information from the EU and Switzerland had historically been certification to the EU- U. S. Privacy Shield framework, which~~ is ~~administered by the U. S. Department of Commerce, and Swiss- U. S. Privacy Shield framework respectively. However, the EU- U. S. Privacy Shield framework was invalidated as a mechanism to legitimize international transfers in July 2020 in the " Schrems II " decision handed down by the Court of Justice of the EU and imposed further restrictions on the use of standard contractual clauses (SCCs). The Schrems II decision~~ also ~~led to~~ a requirement **in certain cases** for companies to carry out a transfer impact assessment (TIA) which, among other things, assess laws governing access to personal information in the recipient country and considers whether supplementary measures that provide privacy protections additional to those under the EU SCCs will need to be implemented to ensure an " essentially equivalent " level of data protection to that afforded in the EU. ~~Similarly, the Swiss- U. S. Privacy Shield framework was declared as inadequate by the Swiss Federal Data Protection and Information Commissioner in light of the Schrems II decision.~~ On ~~October 7, 2022, the U. S. President introduced an Executive Order to facilitate a new Trans- Atlantic Data Privacy Framework (DPF), and on~~ July 10, 2023, the EC adopted its Final Implementing Decision granting the U. S. adequacy (Adequacy Decision) for EU- U. S. transfers of personal information for companies that self- certify to the **Data Privacy Framework (** DPF **)** . Entities relying on EU SCCs for transfer to the U. S. are also able to rely on the analysis in the Adequacy Decision as support for their TIA regarding the equivalence of U. S. national security safeguards and redress. However, any transfers by us or our vendors of personal information subject to the EU GDPR may not comply with European data protection law, may increase our exposure to the EU GDPR' s heightened sanctions for violations of its cross- border data transfer restrictions, and may reduce demand from companies subject to European data protection laws. Complying with the GDPR involves rigorous and time- intensive processes that may cause us to incur certain operational costs and / or require us to change our business practices. There may also be a risk that the measures will not be implemented correctly or that individuals within the business will not be fully compliant with the required procedures. If there are breaches of these measures, we could face significant administrative and monetary sanctions as well as reputational damage which may have a material adverse effect on our operations, financial condition and prospects. Assisting our customers, partners, and vendors in complying with the GDPR, or complying with the GDPR ourselves, may cause us to incur substantial operational costs or require us to change our business practices. There may also be a risk that the measures will not be implemented correctly or that individuals within the business will not be fully compliant with the required procedures. There is a risk that we could be impacted by a cybersecurity incident that results in loss or unauthorized disclosure of personal information, potentially resulting in us facing harms similar to those described above. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements, potential significant fines for non- compliance of up to the greater of € 20 million (under the EU GDPR) or £ 17. 5 million (under the UK GDPR) or 4 % of consolidated annual global turnover and restrictions or prohibitions on data processing. The GDPR identifies a list of points to consider when determining the level of fines to impose (including the nature, gravity and duration of the infringement). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. The UK GDPR also imposes similar restrictions on transfers of personal information from the UK to jurisdictions that the UK Government does not consider " adequate ", including the U. S. It should also be noted that the UK Government has published its own form of EU SCCs known as the UK International Data Transfer Agreement together with an International Data Transfer Addendum to the new EU SCCs. ~~The UK Information Commissioner' s Office (ICO) has also published its version of the TIA and guidance on international transfers, although entities may choose to adopt either the EU or UK style TIA.~~ Further, on September 21, 2023, the UK Secretary of State of Science, Innovation and Technology established a UK- U. S. data bridge (i. e., a UK equivalent of the Adequacy Decision) and adopted UK regulations to implement the UK- U. S. data bridge (~~"~~ UK Adequacy Regulations ~~"~~). Personal information may now be transferred from the UK under the UK- U. S. data bridge through the UK extension to the DPF to organizations self- certified under the UK extension to DPF **. Cybersecurity requirements are laid down in various**

laws in the EU and the UK, the key ones being: (i) the GDPR (as discussed above), which requires controllers and processors to implement appropriate technical and organizational measures to safeguard personal data to a level of security appropriate to the data protection risk; (ii) the UK Network and Information Systems Regulation 2018 (NIS Regulations), and (iii) EU Network and Information Systems Security 2 Directive (NISD2). Under the NISD2, stringent cybersecurity and incident reporting requirements are imposed on ‘ essential’ and ‘ important’ entities, including, for example, entities carrying out research and development activities of medicinal. NISD2 states that any maximum fine which national implementing law provides for should at least be set at € 10 million or 2 % of total worldwide turnover, whichever is higher, where essential entities are concerned. Other sanctions may include (i) a temporary suspension to provide services in the EU (by suspending relevant authorizations / certifications); (ii) an order to make public certain elements of the infringement and / or inform customers; and (iii) injunctions to immediately cease infringing conduct. Importantly, NISD2 also provides that senior members of staff can be held personally liable, and face administrative fines or be temporarily suspended from exercising managerial functions at the legal representative or chief executive officer level . Other countries outside of Europe and the UK continue to enact or are considering enacting similar cross- border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil recently enacted the General Data Protection Law (Lei Geral de Proteção de Dados Pessoais or LGPD) (Law No. 13, 709 / 2018), which broadly regulates the processing of personal information and imposes compliance obligations and penalties comparable to those of the EU GDPR and the UK GDPR. Regulation of privacy, data protection **,** and data security has also become more stringent in the United States. HIPAA imposes requirements to protect the privacy and security of protected health information (~~“~~ PHI ~~”~~) and to provide notification in the event of a breach of PHI. Violations of HIPAA are punishable by civil money penalties and, in some cases, criminal penalties and imprisonment. HHS’ Office for Civil Rights (~~“~~ OCR ~~”~~), which is responsible for enforcing HIPAA, also may enter into resolution agreements requiring the payment of a civil money penalty and / or the establishment of a corrective action plan to address violations of HIPAA. Pursuant to HIPAA, HHS has adopted privacy regulations, known as the privacy rule, to govern the use and disclosure of PHI (the ~~“~~ Privacy Rule ~~”~~). HHS has also adopted data security regulations ~~(the “ Security Rule ”)~~ that require Covered Entities ~~(including health care providers)~~ and Business Associates to implement administrative, physical and technical safeguards to protect the integrity, confidentiality and availability of PHI that is electronically created, received, maintained or transmitted (such as between us and our affiliated practices). **While the vast majority of HIPAA obligations do not apply to pharmaceutical companies or clinical trial data, the requirements inform privacy and security practices across the industry and may impact interactions with health care providers.** Numerous state ~~and certain other federal~~ laws ~~protect the confidentiality of health~~ **are also designed to address privacy and** information **security issues** ~~and other personal information~~ , including but not limited to state medical privacy laws, state laws protecting personal information, state data breach notification laws, state genetic privacy laws, human subjects research laws and federal and state consumer protection laws. For example, the CCPA, which took effect on January 1, 2020, give California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. The CCPA was substantially expanded on January 1, 2023, when the **California Privacy Rights Act (** CPRA **)** amendments to the CCPA became fully operative. The CPRA amendments, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross- contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA’ s private right of action, provide for increased penalties for CCPA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law. Regulation of privacy, data protection and data security has also become more stringent in the United States, with several new laws **following the CCPA and** being enacted at the state level ~~. For instance~~ , ~~additional states have enacted~~ **including several comprehensive privacy** laws ~~related to consumer privacy, such as Colorado, Connecticut, Utah, and Virginia~~ . While these new laws **and proposals** generally include exemptions for HIPAA- covered data **and clinical trial data** , they add layers of complexity to compliance in the U. S. market, and could increase our compliance costs and adversely affect our business ~~. While these laws generally include exemptions for HIPAA- covered and clinical trial data, they impact the overall privacy landscape~~ . Multiple other states and the federal government are considering enacting similar legislation, demonstrating a strong trend towards more stringent state privacy, data protection and data security legislation in the U. S., which could increase our potential liability and adversely affect our business. Other states have passed or amended existing state privacy laws to impose enhanced privacy and cybersecurity obligations for consumer health data, such as, the Washington My Health My Data Act and Nevada’ s Consumer Health Data Privacy Law. For instance, Washington State ~~passed the~~ **' s** “ My Health My Data Act ” **regulates** ~~with respect to~~ “ consumer health data ” which is defined as “ personal information that is linked or reasonably linkable to a consumer and that identifies a consumer’ s past, present, or future physical or mental health **.** ” **The Federal Trade Commission (FTC) has authority under Section 5 of the FTC Act to regulate unfair or deceptive practices,** and ~~which will go into effect~~ **has used this authority to initiate enforcement actions against companies that implement inadequate controls around privacy and information security** in ~~2024~~ **violation of their externally facing policies. The FTC has recently brought several cases alleging violations of Section 5 of the FTC Act** with ~~additional~~ **respect to health information, and has proposed rulemaking on** privacy ~~rights~~ and ~~compliance obligations~~ **data security** . Lawmakers and regulatory bodies at the federal level have been considering more detailed regulation regarding these subjects and the privacy and security of personal information. For example, the FTC ~~recently~~ published an advance notice of proposed rulemaking on “ commercial surveillance ” and data security, and is seeking comment on whether it should implement new trade regulation rules or other regulatory alternatives

concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive. The FTC' s rulemaking may create change throughout the economy and broader data ecosystem. The FTC has also been active with respect to enforcement of its Health Breach Notification Rule and in scrutinizing the use and disclosure of sensitive personal information. **The FTC finalized changes to the Health Breach Notification.** Additionally **, in 2021** , the OCR has issued a Notice of Proposed Rulemaking, which ~~propose~~ **proposed** a number of changes to the HIPAA Privacy Rule, ~~with updates to~~ **and in 2025,** the **OCR issued a Notice of Proposed Rulemaking which proposed a number of changes to** HIPAA ~~Privacy~~ **Security** Rule ~~expected in 2024. The Federal Trade Commission (FTC) has authority under Section 5 of the FTC Act to regulate unfair or deceptive practices, and has used this authority to initiate enforcement actions against companies that implement inadequate controls around privacy and information security in violation of their externally facing policies. The FTC has recently brought several cases alleging violations of Section 5 of the FTC Act with respect to health information, and has proposed rulemaking on privacy and data security~~ . Compliance with applicable U. S. and foreign privacy, data protection, and data security laws and regulations may result in government investigations or cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U. S. and foreign privacy, data protection, and data security laws and regulations could result in government investigations or enforcement actions (which could include civil or criminal penalties), private litigation, claims, or public statements against us and / or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with privacy, data protection, and data security laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, reputation, financial performance and business, and operations. Furthermore, the costs of compliance with, and other burdens imposed by, the laws, regulations and policies that are applicable to the business of our customers may limit the adoption and use of, and reduce the overall demand for, our products and services. If our security measures are compromised, or our information technology systems or those of our vendors, and other relevant third parties fail or suffer security breaches, loss or leakage of data, and other disruptions, this could result in a material disruption of our services, compromise sensitive information related to our business, harm our reputation, trigger our breach notification obligations, prevent us from accessing critical information, and expose us to liability or other adverse effects to our business. In the ordinary course of our business, we may collect, process, and store proprietary, confidential, and sensitive information, including personal information (including health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such information. We face several risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to the third party service providers who handle elements of our operations. We, our partners, our CROs, our CMOs, and other business vendors on which we rely depend on information technology and telecommunication systems for significant elements of our operations, including, for example, systems handling human resources, financial reporting and controls, regulatory compliance and other infrastructure operations. Notwithstanding the implementation of security measures, given the size and complexity of our information technology systems and those of our third party vendors and other contractors and consultants, and the increasing amounts of proprietary, confidential and sensitive information that they maintain, such information technology systems have been subject to and remain vulnerable to breakdown, service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel, third party vendors, contractors, consultants, business partners, and / or other third parties, or from cyber- attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), which may compromise our system infrastructure, or that of our third party vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through accidental actions or omissions by trusted insiders, cyber **-** attacks or cyber intrusions, including by computer hackers, viruses, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Additionally, the increased usage of computers operated on home networks due to the shelter- in- place or similar restrictions related to the COVID- 19 pandemic may make our systems more susceptible to security breaches. For example, in March 2021, MSK provided notice that MSK was one of many customers impacted by a data breach at Accellion, Inc., which provides a document- sharing system. MSK subsequently notified us that certain documents related to one of our discontinued programs were subject to the breach, which compromise we deemed immaterial. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, we and our third party service providers frequently defend against and respond to cyber **-** attacks, and our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, or stolen. Failures or significant downtime of our information technology or telecommunication systems or those used by our third party service providers could cause significant interruptions to our operations, including preventing us from conducting tests or research and development activities and preventing us from managing the administrative aspects of our business. For example, the loss of clinical study data from completed, ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, sophisticated operating system software and

applications that we procure from third parties may contain defects in design or manufacture, including vulnerabilities, " bugs " and other problems that could unexpectedly interfere with the operation of our networks, system, or our processing of personal information or other data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed , and our business could be otherwise adversely affected. We may not be able to anticipate all types of security threats, and we may not be able to implement preventative measures effective against all such security threats. We also may not be effective in responding to, containing or mitigating the risks of an attack. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, hostile foreign governments or agencies, or cybersecurity researchers. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third party vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our products and services could be delayed. The costs related to significant security breaches or disruptions could be material and could exceed the limits of the cybersecurity insurance we maintain, if any, against such risks. If the information technology systems of our third party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third party vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our services and technologies could be delayed. Furthermore, significant disruptions of our internal information technology systems or those of our third party vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation, and / or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. For example, in November 2023, we experienced a cybersecurity incident which resulted in unauthorized access of certain systems within our IT environment and a third party obtaining certain of our documents. Such unauthorized access was detected and contained within several hours and it was determined the third party did not access any of our material confidential information. Following such incident, we' ve taken additional measures to strengthen our IT environment. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, or stolen. Any such access, breach, or other loss of information could result in legal claims or proceedings, liability under domestic or foreign privacy, data protection and data security laws such as HIPAA and HITECH, and penalties. Notice of certain security breaches must be made to affected individuals, the Secretary of HHS, and for extensive breaches, notice may need to be made to the media or state attorneys general. Such notice could harm our reputation and our ability to compete. Although we have implemented security measures, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, conduct research and development activities, collect, process and prepare company financial information, and manage the administrative aspects of our business. Penalties for violations of these laws vary. For instance, penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include significant civil monetary penalties and, in certain circumstances, criminal penalties with fines up to $ 250, 000 per violation and / or imprisonment. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $ 50, 000 and up to one- year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if such a state law affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California' s patient privacy laws, for example, provide for penalties of up to $ 250, 000 and permit injured parties to sue for damages. Similarly, the CCPA allows consumers a private right of action when certain personal information is subject to unauthorized access and exfiltration, theft or disclosure due to a business' failure to implement and maintain reasonable security procedures. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies,

creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, for the treatment of genetic data, along with increased customer demands for enhanced data security infrastructure, could greatly increase our cost of providing our products, decrease demand for our products, reduce our revenues and / or subject us to additional liabilities. Changes in tax laws or regulations that are applied adversely to us or our customers may have an adverse effect on our business, cash flows, financial condition or results of operations. We are subject to income and non- income based taxes in the U. S. and various jurisdictions outside the U. S. Our business and financial condition could be adversely affected by changes in federal, state, local or international tax laws, changes in taxing jurisdictions' administrative interpretations, decisions, policies and positions, changes in accounting principles, applicability of withholding taxes, and changes to our business operations. For example, U. S. legislation such as the Tax Act, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), and the American Rescue Act, made significant changes to the corporate tax rate, the potential realization of net deferred tax assets relating to our operations, taxation of foreign earnings, and deductibility of expenses, and could have a material impact on our financial position or results of operations. Our ability to use net operating loss carryforwards and certain tax assets to offset future taxable income or taxes may be subject to certain limitations. Our ability to use our federal and state net operating losses (NOLs) and certain other tax attributes to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs or other tax attributes. As of December 31, ~~2023~~ **2024** , we had significant U. S. federal and state NOLs due to prior period losses. Under the Tax Cuts and Jobs Act (the Tax Act), federal NOLs generated in tax years beginning on or after January 1, 2018 may be carried forward indefinitely, but the utilization of such federal NOLs is limited to 80 % of current year taxable income. States vary in conformity to all or portions of the Tax Act. The Tax Act did not have a material impact to our financial statements. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), our ability to utilize these NOLs and other tax attributes, such as federal tax credits, in any taxable year may be limited if we have experienced an " ownership change ". Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5 % of a corporation' s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three- year testing period. Similar rules may apply under state tax laws. We performed a Section 382 analysis of transactions in our stock through December 31, ~~2023~~ **2024** and concluded that we have experienced ownership changes since inception that we believe under Section 382 of the Code will result in limitations on our ability to use certain pre- change NOLs and credits. In addition, we may experience subsequent ownership changes as a result of future equity offerings or other changes in the ownership of our stock, some of which are beyond our control. As a result, the amount of the NOLs and tax credit carryforwards presented in our financial statements could be limited and, in the case of NOLs generated before January 1, 2018 may expire unused. Any such material limitation or expiration of our NOLs may harm our future operating results by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit the use of accumulated state tax attributes. Regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, may cause our existing tax attributes to expire, decrease in value or otherwise be unavailable to offset future income tax liabilities. Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses. Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man- made disasters or business interruptions, for which we are predominantly self-insured. Two of our corporate locations are located in California, an area prone to earthquakes and fires. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third- party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption, including, for example, the COVID- 19 pandemic. **The biopharmaceutical industry is subject to extensive regulatory obligations and policies that are subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updaters and changes in policy priorities. On June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) " must exercise their independent judgment " and " may not defer to an agency interpretation of the law simply because a statute is ambiguous. " The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the HHS, CMS, FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny. In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles. For example, the current U. S. presidential administration has committed to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA, and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.**