Risk Factors Comparison 2024-03-05 to 2023-03-09 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report **on Form 10- K** , including our **consolidated** financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " **and the information contained in our other public filings** before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Summary of Principal Risks Associated with Our Business • We are a biotechnology company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability; • ~~Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control, including external factors that may affect our clinical trial enrollment; •~~ We will require substantial additional financing to achieve our goals, and a failure to obtain such necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, **any future** commercialization efforts or other operations; • **We are restricted in our corporate activities by our existing debt facility and are considering all strategic alternatives. If we do not maintain access to funding our debt facilities, we may be required to cease operations and seek relief under Chapter 11 of the U. S. Bankruptcy Code; • Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control; •** Our **tumor- specific cancer** immunotherapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval; • Our business ~~remains~~ **is** highly dependent on the successful development, regulatory approval and commercialization of our individualized ~~immunotherapy~~ **vaccine** product candidate and GRANITE, our " off- the- shelf " ~~immunotherapy~~ **vaccine** product candidate, SLATE **and our COVID- 19 vaccine product candidate, CORAL** , which are in clinical trials; • We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay **or prevent** commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations; • We rely, and intend to rely, on third parties in the conduct **of all** of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements, or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our immunotherapy product candidates; • We currently perform **most** ~~the majority~~ of the manufacturing of our product candidates internally and rely on qualified third parties to supply some components of our product candidates. Our inability to manufacture sufficient quantities of ~~GRANITE, SLATE or~~ any ~~other~~ **of our** current or future product candidates, or the loss of our third- party suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially adversely affect our business; • We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete; • Our success depends on our ability to protect our intellectual property and our proprietary technologies and to avoid infringing the rights of others; and • Our stock price is volatile, and you may not be able to resell shares of our common stock at or above the price you paid. Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements We are a biotechnology company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability. Product development in the biotechnology industry is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical- stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale, have not yet generated any revenue from product sales and have incurred losses in each year since our inception in August 2015. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, ~~,~~ complications, delays and other known and unknown factors and risks frequently experienced by early- stage biopharmaceutical companies in rapidly evolving fields. We have ~~had~~ **incurred** significant operating losses since our inception (for additional information, see " Liquidity " in Note 1 to our consolidated financial statements). Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Our programs will require substantial additional development time and resources before we (or our collaboration partners) ~~would~~ **will** be able to apply for or receive regulatory approvals and begin generating revenue from product sales **, if we are ever able to do so** . In addition, we incur substantial costs associated with operating as a public company. We also do not yet have a sales organization or

commercial infrastructure and, accordingly, if **any of** our product candidates are approved, we will **need to** incur significant expenses to develop a sales organization ~~or~~ **and** commercial infrastructure in advance of generating any commercial product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our current and any future immunotherapy product candidates, conduct clinical trials and pursue research and development activities. Even if we achieve profitability at some point in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital **. We have identified conditions that raise substantial doubt about our ability to continue as a going concern. We will require substantial funds to finance our research and development programs and support our operations. As of December 31, 2023, we had $ 79. 3 million in cash, cash equivalents and marketable securities. We do not believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations through the next twelve (12) months. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year from the date of the issuance of this Annual Report on Form 10- K. As of the date of this Annual Report on Form 10- K, the Company believes that its existing cash, cash equivalents and investments, before considering any potential default under its Loan Agreement, will only be sufficient to fund its planned operating and capital needs into the third quarter of 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward- looking statement that involves risks and uncertainties, and actual results could vary materially based on a number of factors, including any potential adverse impact from any event of default under our Loan Agreement. In particular, if we are unable to raise additional funds, secure a waiver or renegotiate the terms of our Loan Agreement, we expect to be in default under the minimum liquidity requirement included in the Loan Agreement in the second quarter of 2024. Upon such a default, our existing cash, cash equivalents and investments will only be sufficient to fund our operations into the second quarter of 2024. The accompanying consolidated financial statements and related notes have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements and related notes do not reflect any adjustments relating to the recoverability and classification of assets or amounts and classification of liabilities that might be necessary if we are unable to continue as a going concern** . We will require substantial additional financing to achieve our goals, and a failure to obtain such necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, **any future** commercialization efforts or other operations. Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for tumor- specific cancer immunotherapies and infectious disease programs in addition to establishing our in- house manufacturing capabilities. Our preclinical studies, clinical trials and additional research and development activities will require substantial funds to complete. We ~~believe~~ **anticipate** that we will continue to expend substantial resources for the foreseeable future in connection with the development of our current and any ~~other~~ future ~~immunotherapy~~ product candidates we may choose to pursue, as well as the continued development of our manufacturing capabilities and other corporate uses. Specifically, in the near term, we expect to incur substantial expenses as we advance GRANITE ~~and~~ **,** SLATE **, and CORAL** through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization, continue our research and development efforts and invest in our manufacturing facility. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any of our preclinical studies or clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of GRANITE, SLATE **, CORAL** or any other current or future immunotherapy product candidates. **Our** ~~We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations for at least twelve (12) months. However, our~~ operating plans and other demands on our capital resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Our future capital requirements depend on many factors, including: • the scope, progress, results and costs of developing ~~each~~ of our **current and any future** product candidates, including conducting preclinical studies and clinical trials, either on our own or in collaboration with others; • potential delays in our ongoing clinical trials, including for reasons beyond our control **, such supply chain interruptions, geo- political actions, including war and regional conflicts around the world or cybersecurity events** ; • the timing of, ~~and the~~ costs involved in, ~~obtaining~~ **and outcome of** regulatory ~~approvals for~~ **review of** our product candidates; • the number and characteristics of any additional product candidates we develop or acquire; • the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreement; • the cost **and timing** of ~~manufacturing~~ **future commercialization activities, including legal, compliance, marketing, sales and distribution costs, for** any ~~of our products~~ **product candidates for which** we **receive marketing approvals** ~~successfully commercialize, including the cost of scaling up our internal manufacturing operations~~ ; • ~~the cost of building a sales force in anticipation of product commercialization; • the cost of commercialization activities, including legal, compliance, marketing, sales and distribution costs; •~~ our ability to maintain existing, and establish new, strategic collaborations

~~,~~ **and** licensing or other arrangements and the financial terms of any such arrangement, including the timing and amount of any future milestone, royalty or other payments due under any such arrangement; • any product liability or other lawsuits related to our ~~products~~ **product candidates** ; • the expenses needed to attract, hire and retain skilled personnel; • the costs associated with being a public company; • the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; ~~and~~ • the timing, receipt and amount of sales of our future approved products, if any **; and • general economic conditions and trends, including inflation and market volatility, rising interest rates, the ongoing labor shortage, recent instability in the global banking sector, the federal debt ceiling and budget and the potential for government shutdowns** . Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to **, among other things** : • delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or eliminate one or more of our development programs altogether; or • delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize **any of** our ~~immunotherapy~~ product candidates **that receive regulatory approval** , or reduce our flexibility in developing or maintaining our sales and marketing strategy **. Our ability to raise additional funds may be adversely impacted by worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, including as a result of increases in inflation and market volatility, rising interest rates, the uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, the ongoing labor shortage, disruptions to global supply chains, and regional conflicts around the world. Moreover, there has been recent turmoil in the global banking system. For example, in March 2023, Silicon Valley Bank (SVB), was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver for SVB. While the FDIC subsequently stated that all depositors of SVB would be made whole, there is no guarantee that the federal government would similarly guarantee all depositors in the event of future bank closures. Moreover, events such as the closure of SVB, in addition to global macroeconomic conditions discussed above, may cause further turbulence and uncertainty in the capital markets. Further deterioration of the macroeconomic environment and any regulatory action taken in response thereto may adversely affect our business, operating results, and financial condition** . We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights or jointly own some aspects of our technologies or product candidates that we would otherwise pursue on our own. We may not realize revenue from sales of products or royalties from licensed products in the foreseeable future, and no such revenue will be realized unless and until a product candidate is clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through the sale of equity securities. We will be required to seek **substantial** additional funding in the future and currently intend to do so through collaborations, public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants, repayment obligations, or other similar restrictions that may affect our business and limit our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. ~~only be sufficient to fund our operations into the second quarter of 2024.Such increased interest charges,acceclerated repayment,proceedings against the collateral or other actions will have a negative impact on our business,financial condition and results of operations.Our existing and any future indebtedness may limit our cash flow available to invest in the ongoing needs of our business.Our outstanding debt combined with our other financial obligations and financial commitments could have~~ significant adverse consequences,including:• requiring us to dedicate cash flow from operations or cash on hand to the payment of interest on,and principal of,our debt,which will reduce the amounts available to fund working capital,capital expenditures,product development efforts and other general corporate purposes;• increasing our vulnerability to adverse changes in general economic,industry and market conditions;• subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;• limiting our flexibility in planning for,or reacting to,changes in our business and our industry;and • placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.We intend to satisfy our current and future debt service obligations with our existing cash and funds from external sources.Nonetheless,we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing or any future debt facility.Funds from external sources may not be available on acceptable terms,if at **all.In addition,a failure to comply with the covenants under the Loan Agreement or any future loan agreements we may enter into could result in an event of default and acceleration of amounts due.If an event of default occurs and the lenders accelerate the amounts due under such loan agreements,we may not be able to make accelerated payments,and such lenders could seek to enforce security interests in the collateral securing such indebtedness** Our operating results may fluctuate significantly **from period to period** , which makes our future operating results difficult to predict ~~and ,~~ could cause our operating results to fall below expectations **, and may cause our stock price to fluctuate or decline** . Our quarterly and annual operating results may fluctuate significantly **from period to period** , which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are beyond our control and may be difficult to predict, including: • the timing and cost of, and level of investment in **our ongoing** ~~, research,~~ development ~~and commercialization activities~~ **of our product candidates or any future development programs** , which may change from time to time; • **if any of our product candidates are approved,** the timing of receipt of **such** approvals from regulatory authorities

in the United States and internationally; • the timing and status of enrollment for our clinical trials; • the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity of production, the cost of continuing to establish and scale up our internal manufacturing capabilities, and the terms of any agreements we enter into with third- party suppliers; • the timing and amount of any milestone, royalty or other payments due under any current or future collaboration or license ~~agreement~~ **agreements** ; • coverage and reimbursement policies with respect to our ~~immunotherapy~~ **vaccine** product candidates, **that are approved,** if ~~approved~~ **any** , and potential future drugs that compete with our products; • expenditures that we may incur to acquire, develop or commercialize additional products and technologies; • the level of demand for **any of** our immunotherapy products, ~~if~~ **that may be** approved, which may vary significantly over time; • the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; ~~and~~ • future accounting pronouncements or changes in our accounting policies **; • regulatory developments affecting our product candidates or those of our competitors; and • changes in general market and economic conditions, including supply chain disruptions, regional conflicts around the world, recent instability in the banking sector, inflation and market volatility, rising interest rates, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, cybersecurity events, and the ongoing labor shortage** . The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any revenue or earnings guidance we previously provided. Risks Related to Our Business Our business is highly dependent on the successful development, regulatory approval and commercialization of our product candidates, primarily our individualized ~~immunotherapy~~ **vaccine** product candidate, GRANITE, ~~and~~ our " off- the- shelf " ~~immunotherapy~~ **vaccine** product candidate, SLATE **and our COVID- 19 vaccine product candidate, CORAL** , which are in clinical trials. We currently have no products approved for sale and may never be able to develop marketable products. All ~~three~~ of our clinical programs are in either Phase 1 or Phase 2 clinical trials. As such, we face significant clinical risk with our programs and our tumor and viral- specific immunotherapy approach generally. The success of our business, including our ability to finance our operations and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of GRANITE ~~and~~ **,** SLATE **and CORAL** , as well as other product candidates derived from our ~~immunotherapy~~ **vaccine** approach, which may never occur. To date, our product candidates have only been tested in a small number of humans, and, given our early stage of development, it may be many years, if at all, before we have demonstrated ~~the~~ safety and efficacy **levels** , especially of an individualized immunotherapy **vaccine** treatment, sufficient to warrant approval for commercialization. In the future, we may also become dependent on other product candidates that we may develop or acquire. We have not previously submitted a BLA to the FDA or made a similar filing seeking regulatory approval to comparable foreign authorities ~~,~~ for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, any product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market a product candidate, our revenue will be dependent, in part, upon a number of factors outside of our control, including, in particular, the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved. We plan to seek regulatory approval to commercialize our product candidates both in the United States and in selected foreign countries. While the scope of regulatory approval generally is similar in other countries, to obtain separate regulatory approval in other countries we must comply with numerous and ~~varying~~ **varied** regulatory requirements of **each** such ~~countries~~ **country** regarding quality, safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials ~~and~~ **,** commercial sales, ~~as well as~~ pricing and distribution ~~of our product candidates~~ , and we may be required to expend significant resources to obtain regulatory approval and **, if approval is obtained,** to comply with ~~ongoing~~ **applicable** regulations in these jurisdictions. The clinical and commercial success of our current and any future product candidates will depend on several factors, including the following: • our ability to raise any additional required capital on acceptable terms, or at all; • timely completion of our preclinical studies and clinical trials, which may be significantly slower, or cost more, than we currently anticipate and **which** will depend substantially upon the performance of third- party contractors; • our ability to timely execute our ongoing clinical trials and enroll a sufficient number of patients on a timely basis to evaluate the potential of our product candidates in clinical development; • whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support approval of our product candidates; • our ability to ~~complete an IND, or similar foreign applications, enabling studies, and~~ successfully submit an IND or similar foreign ~~applications~~ **application, enabling studies** for **any** future product candidates; • acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities; • our ability to consistently manufacture our product candidates on a timely basis; • our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMPs or similar foreign requirements; • our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the quality, safety, efficacy and acceptable risk- benefit profile of our product candidates; • the prevalence, duration and severity of potential side effects or

other safety issues experienced with our product candidates or future approved products, if any; • the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities; • achieving and maintaining, and, where applicable, ensuring that our third- party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our current or any future product candidates or approved products, if any; • the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our individualized cancer immunotherapy approach; • our ability to successfully develop a commercial strategy and thereafter commercialize GRANITE, SLATE, CORAL or any future product candidates (including our partnered HIV therapeutic vaccine) **that receives approvals for marketing, sale and distribution** in the United States ~~and~~ **or** internationally ~~, if approved for marketing, sale and distribution in such countries and territories~~ , whether alone or in collaboration with others; • the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third- party payors for any of our product candidates that may be approved; • the convenience of ~~our~~ **the** treatment or dosing regimen **of our product candidates** ; • acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments; • patient demand for our current or future product candidates, if approved; • our ability to establish and enforce intellectual property rights in and to our **current and future** product candidates; and • our ability to avoid third- party patent interference, intellectual property challenges or intellectual property infringement claims. These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any product candidates. Accordingly, we cannot provide assurances that we will **ever** be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business or achieve profitability. Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. We may experience delays in enrolling or completing our clinical trials. Additionally, we cannot be certain that studies or trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. ~~Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to: • inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials; • the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials; • delays in obtaining regulatory authorization to commence a trial; • reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • obtaining IRB, ethics committee and, where required, IBC approval at each trial site; • recruiting an adequate number of suitable patients to participate in a trial, which can be impacted by external factors beyond our control, including, due to the COVID- 19 or other pandemics; • having subjects complete a trial or return for post- treatment follow- up; • clinical sites deviating from trial protocol or dropping out of a trial; • addressing subject safety concerns that arise during the course of a trial; • adding a sufficient number of clinical trial sites; • supplying sufficient quantities of product candidates or other materials for use in preclinical studies or clinical trials; or • accessing checkpoint inhibitors for use in combination with our product candidates in preclinical studies or clinical trials, including checkpoint inhibitors that have not been approved by the FDA for such use. As demonstrated during the COVID- 19 pandemic, a public health crisis (or other situation having lasting and widespread societal impact) can result in challenges and delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials, as well as delays in the commencement of our preclinical studies.~~ We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent us from receiving marketing approval or commercializing our product candidates, including: **• we may experience an inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;** • we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials **or may fail to reach a consensus with regulators on trial design** ; • we may be affected by safety concerns that have a class effect; for example, if a competitor reports negative results with respect to a product candidate similar to those we are developing, such setbacks could negatively impact our own product development; • **we may experience delays in reaching, or may fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; •** clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our development programs, including our individualized cancer immunotherapy program; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate; • we or our third- party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, or be unable to produce sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all; • we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements, 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 risks; • the cost of clinical trials of our product candidates may be greater than we anticipate; • the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate; • regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate **; • regulators or IRBs may require that we or our investigators suspend or**

terminate clinical trials for various reasons, including noncompliance with regulatory requirements ; and • future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently ~~contemplate~~ **anticipate** , if we are unable to successfully complete clinical trials **or other testing** of our product candidates ~~or other testing~~ , if the results of these trials or tests are not positive or are only moderately positive, or if there are safety concerns, we may: • incur unplanned costs; • be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all; • obtain marketing approval in some countries and not in others; • obtain marketing approval for indications or patient populations that are not as broad as intended or desired; • obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings; • be subject to additional post-marketing testing requirements, which could be expensive and time consuming; or • have the treatment removed from the market after obtaining marketing approval. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board (DSMB), or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. **For example, in February 2024, following receipt of a clinical hold letter and follow up communications with the FDA with respect to our proposed Phase 2b trial of our CORAL COVID- 19 vaccine product candidate, we announced the delay of the initiation of such clinical trial until the fall of 2024. In the clinical hold letter, the FDA informed us that, with respect to this Phase 2b clinical trial, we would be required to use GMP- grade materials in the manufacture of the vaccine, as well as implement minor changes in the clinical trial protocol.** Further, conducting clinical trials in foreign countries, as we have done ~~in~~ **through** our collaborations related to CORAL and may do for certain of our other product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, we fail to ensure such relationships and compensation are accurately disclosed, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates. If any of our preclinical studies or clinical trials of our product candidates are delayed or terminated, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates could be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If our product candidates or our immunotherapy prediction platform generally prove to be ineffective, unsafe or commercially unviable, our entire platform and approach would have little, if any, value, which would have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, the FDA' s and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union recently evolved. The CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate CTA to be submitted in each member state to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state' s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three- year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors were still able to choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third- party service providers, such as CROs, may impact our developments plans. It is currently unclear to what extent the United Kingdom, as a free- standing regulatory regime outside of the European Union, will ~~seek to~~ amend its regulations so that they diverge from the regulatory regime in the European Union. The UK regulatory framework in relation to clinical trials is derived from the EU Clinical Trials Directive (as implemented into UK law, through secondary legislation) in place prior to the date of application of the CTR. On January 17, 2022, the MHRA launched an eight- week consultation on

reframing the UK legislation for clinical trials. The ~~consultation closed~~ **UK Government analyzed over 2000 responses and published its response** on March ~~14~~ **21** , ~~2022~~ **2023** ~~(although a~~ **. The Government** response **stated it** ~~has not yet been published) and~~ aims to streamline clinical trials approvals, ~~enable innovation,~~ enhance clinical trials transparency, enable greater risk proportionality ~~,~~ and ~~promote patient~~ **flexibility,** and ~~public involvement in~~ **provide a framework that is agile and responsive to innovation. The Government is expected to submit the full new draft legislation to the UK Parliament before the end of 2023, along with detailed regulatory guidance. The process was started with the proposal of October 12, 2023 for a notification scheme and accelerated assessment of lowest- risk** clinical trials. The ~~outcome of the consultation~~ **upcoming additional legislative proposals and guidance** will **give indications** ~~be closely watched and will determine~~ whether **the new regime in** the United Kingdom **will** ~~chooses to~~ align with the new EU CTR or **will** diverge from it to maintain regulatory flexibility. A decision by the United Kingdom not to closely align its regulations with the CTR may have an effect on the cost of conducting clinical trials in the United Kingdom as opposed to other countries and / or make it harder to seek a marketing authorization in the European Union for our product candidates on the basis of clinical trials conducted in the United Kingdom. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted **. A significant portion of the funding for the continued development of our next- generation samRNA vaccine candidate containing Spike plus other viral targets to protect against COVID- 19 is currently expected to come from BARDA funds, whether under the BARDA Contract or as administered through the RRPV Consortium. If BARDA were to decline to pursue any of the gated stages, eliminate, reduce, delay, or object to extensions for funding available to us under the BARDA Contract, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate the continued development of the product candidate or obtain alternative sources of funding. We anticipate that a significant portion of the funding for the continued development of our next generation self- amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID- 19 will stem from the BARDA Contract. As awarded, the existing BARDA Contract provides for funding of up to an estimated $ 433. 0 million to conduct a 10, 000 participant randomized Phase 2b comparative study evaluating our self- amplifying RNA vaccine candidate containing Spike plus other viral targets to protect against COVID- 19. The base period under the BARDA Contract includes government funding of only up to approximately $ 10. 0 million for performance of certain milestones such as preparation of protocol synopsis and submission of an investigational new drug (" IND") application, with the remaining $ 423 million available at BARDA' s option to conduct the comparative study. In late 2023, BARDA informed us that any potential funding beyond the base period of the BARDA Contract is expected to be administered under a new award made by the RRPV Consortium. In early 2024, we applied to the RRPV Consortium for funding of our Phase 2b CORAL Study extending beyond the base period of the BARDA Contract, seeking substantively similar agreement terms as the BARDA Contract. There is no certainty that the RRPV Consortium, which selects awardees at BARDA' s discretion, will accept our application and on what terms. The RRPV Request for Project Proposals included the potential to begin a Phase 2b study by March 31, 2024, or at BARDA' s discretion by October 1, 2024, to align with the Fall 2024 COVID- 19 strain change. Our ability to receive any of the initially identified $ 423. 0 million in additional funding provided for under the BARDA Contract is dependent on BARDA electing to continue to fund additional two gated stages or the RRPV Consortium accepting our application, which would occur only at BARDA' s direction and its sole discretion. The base period for performance under the BARDA Contract is currently scheduled to run from September 2023 to March 31, 2024, though BARDA may grant a no- cost extension to the base period to allow for regulatory negotiations to continue. The option periods for the two additional gated stages under the BARDA Contract were scheduled to run from January 2024 to March 2026 and from July 2024 to July 2026. These periods of performance may be adjusted if Gritstone' s RRPV application is accepted. As a standard government contract, BARDA is entitled to terminate the BARDA Contract for convenience at any time, in whole or in part, and is not required to provide continued funding beyond reimbursement of amounts currently incurred and obligated by us as a result of contract performance. In addition, activities covered under the base period may ultimately cost more than is covered by the BARDA Contract and may require a longer performance period to complete than is remaining under the terms of the BARDA Contract. BARDA is not required to provide funding above the approximately $ 10. 0 million currently obligated for the base period of the BARDA Contract, nor is BARDA required to extend the base period of performance or elect to pursue any of the gated stages. As noted in Note 7 to the consolidated financial statements, we received $ 9. 0 million of the $ 10. 0 million obligated by December 31, 2023. If activities covered under the base period cost us more than the approximately $ 10. 0 million currently obligated for the base period under the BARDA Contract, and we are unable to secure additional funding from BARDA to complete performance of the base period activities, we would have to bear the cost to complete the activities. Further, if we are unable to complete the base period activities during the base period due to circumstances that may be either within or outside of our control, including, among others, any potential delays in sourcing an approved comparator vaccine, and BARDA is unwilling to allow for additional time, then BARDA may decide to terminate the BARDA Contract or deny the application to the RRPV Consortium. Moreover, the continuation of the BARDA Contract or receipt of a new award administered by the RRPV Consortium for the effort intended for the BARDA Contract option periods would primarily depend on our ability to initiate a Phase 2b study within BARDA' s timeline and on our compliance with certain operating procedures and protocols, assuming federal funds remain available. Further, as an organization, we are relatively new to government contracting and the related regulatory compliance obligations, and are continuing to develop and implement our internal compliance processes. BARDA may suspend or terminate the BARDA Contract, opt not to exercise the remaining option periods, or deny the application to the RRPV Consortium should we fail to achieve key milestones or fail to comply with the operating**

procedures and processes approved by BARDA and its audit agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols, and there can also be no assurance that the BARDA Contract will not be terminated, that the BARDA Contract will be extended through the exercise of the gating periods, that any such extensions would be on terms favorable to us, or that we will otherwise obtain the funding that we anticipate to obtain under the BARDA Contract or an award from the RRPV Consortium. The availability and focus for any BARDA funding will likely be finite and may require us to compete with other technologies, both similar and disparate. If the BARDA Contract is terminated or suspended, if there is any reduction or delay in funding under the BARDA Contract, or if BARDA determines not to elect to pursue any of the gated stages under the BARDA Contract or select Gritstone for a new award administered by the RRPV Consortium, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non- dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities for our next- generation self- amplifying mRNA vaccine candidate containing Spike plus other viral targets to protect against COVID- 19, which could materially harm our business. It may take considerable time and expense to resolve the clinical hold that has been placed by the FDA on our Phase 2b CORAL trial we proposed in our IND for our CORAL COVID- 19 vaccine product candidate and no assurance can be given that the FDA will remove the clinical hold, in which case our business and financial prospects may be materially adversely affected. In December 2023, we were notified by the FDA that our Phase 2b CORAL Study had been placed on clinical hold. In January 2024, we received the formal clinical hold letter from the FDA, identifying certain CMC and clinical deficiencies. The FDA informed us that, among other changes, we will be required to use GMP- grade materials in the manufacture of the vaccine as well as implement minor changes in the clinical study protocol. We are working on preparing a complete response to the FDA' s letter in an effort to remove the clinical hold from our IND application. This includes re- manufacturing our CORAL vaccine candidate to be used in the Phase 2b CORAL Study with GMP- grade materials. If the FDA does not accept the responses we plan to provide, it may take a further considerable period of time, the length of which is not certain at this time, and additional expense for us to fully address the FDA' s concerns. It is possible that we will be unable to fully address the FDA' s concerns and, as a result, that the clinical hold may never be lifted and we may never be able to initiate our Phase 2b CORAL Study in the United States, which could have a material adverse effect on our business, financial condition, results of operations and prospects . Our tumor- specific cancer immunotherapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval. Regarding our tumor- specific cancer immunotherapies, our foundational science and product development approach are based on our ability to predict the presence of a patient' s TSNA and develop a TSNA- directed therapy that will elicit a meaningful T cell response. We believe that this approach may offer an improved therapeutic effect by driving an intense, focused T cell attack selectively upon a patient' s tumor. However, this approach to treating cancer is novel and the scientific research that forms the basis of our efforts to predict the presence of TSNA and to develop TSNA- directed cancer immunotherapy candidates is both preliminary and limited. The results of our preclinical animal studies may not translate into humans. For example, our prediction model may fail to accurately predict the presence of TSNA, resulting in little or no tumor- targeted T cell response, or our therapy may fail to elicit a significant or durable enough T cell response to effectively destroy a tumor. As such, we cannot assure you, even if we are able to develop individualized cancer immunotherapy candidates capable of recognizing TSNA and eliciting a T cell response, that such therapy would safely and effectively treat cancers. We may spend substantial funds attempting to develop this approach and never succeed in developing a marketable therapeutic. No regulatory authority has granted approval for a cancer immunotherapy based on a heterologous prime- boost approach, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications, lines of therapy or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post- marketing testing requirements to maintain regulatory approval. If our personalized immunotherapy candidates prove to be ineffective, unsafe or commercially unviable, our entire technology platform and pipeline would have little, if any, value, which would have a material adverse effect on our business, financial condition, results of operations and prospects. The regulatory approval process and clinical trial requirements for novel product candidates can be more expensive and take longer than for other, better known or more extensively studied product candidates, and we cannot predict how long it will take or how much it will cost to complete clinical developments and obtain regulatory approvals for a cell therapy product candidate in the United States or how long it will take to commercialize a product candidate, if and when approved. Regulatory requirements governing cell therapy products have changed frequently and may continue to change in the future. For example, the FDA established the Office of Tissues and Advanced Therapies **(OTAT)** within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of cell therapies and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review **. OTAT was subsequently reorganized to become the Office of Therapeutic Products (OTP) and transitioned into a super office structure. New offices created within the super office structure align disciplines and product types, allowing our workforce to address the exponential growth in cell and gene therapies. This updated structure will enable OTP to provide oversight and coordination across programs, ensure flexibility for current and future growth in staff, distribute workload more evenly, support industry needs and commitments, enhance expertise in highly specialized disciplines** . These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional

preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post- approval limitations or restrictions. Additionally, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies. Additionally, adverse developments in clinical trials conducted by others of cell therapy products or products created using similar technology, or adverse public perception of the field of cell therapies editing, may cause the FDA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing technologies such as ours, either of which could materially harm our business. As we advance our product candidates, we will be required to consult with various regulatory authorities, and we must comply with applicable laws, rules and regulations, which may change from time to time, including during the course of development of our product candidates. If we fail to do so, we may be required to delay or discontinue the clinical development of certain of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Even if we comply with applicable laws, rules, and regulations, and even if we maintain close coordination with the applicable regulatory authorities with oversight over our product candidates, our development programs may fail to succeed. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market would materially adversely affect our business, financial condition, results of operations and prospects. Results of earlier studies and trials of our product candidates may not be predictive of future trial results. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any promising results we may have observed in earlier studies and trials, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, the results of our preclinical animal studies, including our non- human primate studies, may not be predictive of the results of outcomes in human clinical trials. For example, our tumor- specific cancer immunotherapy candidates and any future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates. Our product candidates are biologics with complex and time- consuming manufacturing processes, and we may encounter difficulties in production, particularly with respect to process development or scaling- out of our manufacturing capabilities. If we or any of our third- party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. Our immunotherapy product candidates, GRANITE, SLATE and CORAL, are considered to be biologics, ~~and~~ the manufacturing processes **for which** are complex, time- consuming, highly-regulated and subject to multiple risks. Our product candidates for SLATE and CORAL are designed using known genetic sequences available from public databases, while the manufacture of our product candidate **for** GRANITE involves extraction of genetic material from patient tumor samples. GRANITE, SLATE and CORAL require genetic manipulations at the gene sequence level, live cell culture operations, specialized formulations and aseptic fill finish operations. As a result of these complexities, the cost to manufacture biologics in general, and our individualized immunotherapy GRANITE in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and more difficult and time- consuming to reproduce. In addition, our manufacturing processes for GRANITE and SLATE are in their early stages of development and will be susceptible to product loss or failure, or product variation that may adversely impact patient outcomes. Our supply chain may not function efficiently due to logistical issues associated with but not limited to the collection of a tumor biopsy from the patient, shipping such material to the manufacturing site, sequencing the biopsy specimen, manufacturing the immunotherapy components, shipping the final immunotherapy back to the patient, and injecting the patient with the immunotherapy. Manufacturing issues or different product characteristics resulting from process development activities or even minor deviations during normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If for any reason we lose a patient' s biopsy or an in- process product at any point in the process, the manufacturing process for that patient would need to be restarted, and the resulting delay could adversely affect that patient' s outcome. Because GRANITE is manufactured specifically for an individual patient, we will be required to maintain a chain of identity and chain of custody with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity and chain of custody is difficult and complex, and the failure to do so could result in adverse patient outcomes, loss of product or regulatory action, including withdrawal of our products from the market, if licensed. As part of our process development efforts for GRANITE and SLATE,

we also may make changes to our manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For ~~instance~~ **example, in July 2023, the FDA issued Draft Guidance for Industry, Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products. Further** , changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. Furthermore, if microbial, viral or other contaminations are discovered in our manufacturing facilities, or those of our CMOs, or in our product candidates manufactured there, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any such contaminations or stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay or prevent commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations. To gain approval to market our product candidates, we must provide the FDA and foreign regulatory authorities with clinical data that adequately demonstrate the safety, purity, potency and efficacy of the product candidate for the intended indication applied for in the applicable regulatory filing. Product development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical development programs. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct. We have not previously submitted a BLA or any other marketing application to the FDA or similar filings to comparable foreign regulatory authorities. A BLA or other similar regulatory filing requesting approval to market a product candidate must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, effective, pure and potent for each desired indication. The BLA or other similar regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. FDA and foreign regulatory authorities may also conduct pre- license inspections of us and / or our CMOs to ensure the manufacture of a product candidate complies with applicable regulatory requirements, including cGMP or similar foreign requirements. Adverse inspection findings could result in the delay or non- approval of a BLA or other similar regulatory filing and require the implementation of costly corrective actions before potential approval can be granted. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions. The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates for many reasons, including: • our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that any of our product candidates are safe, pure, potent and effective for the requested indication; • the FDA' s or the applicable foreign regulatory agency' s disagreement with our trial protocols or the interpretation or reliability of data from preclinical studies or clinical trials; • our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks; • the FDA' s or the applicable foreign regulatory agency' s requirement for additional preclinical studies or clinical trials; • the FDA' s or the applicable foreign regulatory agency' s non- approval of the formulation, labeling or specifications of GRANITE, SLATE, **CORAL** or any of our other current or future product candidates; • the FDA' s or the applicable foreign regulatory agency' s failure to approve our manufacturing processes and facilities or the facilities of third- party manufacturers upon which we rely; or • the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval. For example, the FDA launched Project Optimus as an initiative to reform the dose optimization and dose selection paradigm in oncology product development as the FDA' s view is that the current paradigm for dose selection results in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating registration / pivotal trials. Through collaboration with industry, academia, and other stakeholders, the FDA' s goal for this initiative is to advance an oncology dose- finding and dose optimization paradigm that emphasizes dose selections that maximize efficacy as well as safety and tolerability. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies pre- or post- approval. The FDA also continues to develop and finalize guidance documents and implement initiatives regarding the development and clinical research of oncology product candidates. **The FDA issued Draft Guidance for Industry, Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases in January 2023, to assist sponsors in identifying the optimal dosages for these products during clinical development and prior to submitting an application for approval for a new indication and usage.** Additionally ~~, in part due to questions raised by the process underlying the approval of the Alzheimer' s disease drug Aduhelm ® ~~, government authorities and other stakeholders have been recently scrutinizing the accelerated approval pathway, with some stakeholders advocating for reforms. **For example** ~~Even prior to the Aduhelm approval~~ , FDA has held Oncologic Drugs Advisory Committee meetings to discuss accelerated approvals for which confirmatory trials have not verified clinical benefit. Such scrutiny, among other factors, has resulted in voluntary withdrawals of certain products and indications approved

on an accelerated basis. FDA also launched an initiative, known as Project Confirm, to promote the transparency of outcomes related to accelerated approvals for oncology indications **and issued draft guidance for industry on March 24, 2023, Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics, regarding clinical trial design considerations to support accelerated approval applications** . Moreover ~~, spurred by the Aduhelm controversy~~ , the U. S. Department of Health and Human Services Office of Inspector General has initiated, and partially completed, an assessment of how the FDA implements the accelerated approval pathway. In addition, Section 3210 of the Consolidated Appropriations Act, 2023, revised the accelerated approval pathway. Although this legislation did not change the standard for accelerated approval, it, among other things, requires FDA to specify the conditions for required post- marketing trials, permits FDA to require such trials to be underway prior to, or within a specific period after, approval, requires sponsors to provide reports on post- marketing trial progress no later than 180 days after approval and every 180 days thereafter until such trials are completed, makes the failure to conduct required post- marketing trials with due diligence and the failure to submit the required reports prohibited acts, and details procedures FDA must follow to withdraw an accelerated approval on an expedited basis. **In February 2024, FDA exercised its authority under the amended procedures for withdrawal of accelerated approval to withdraw approval of Pepaxto (melphalan flufenamide), which was approved for use in combination with dexamethasone to treat certain patients with multiple myeloma. FDA determined that the following grounds for withdrawal were met: 1) the confirmatory study conducted as a condition of accelerated approval did not confirm Pepaxto' s clinical benefit, and 2) the available evidence demonstrated that Pepaxto is not shown to be safe or effective under its conditions of use. or** At this time, it is not clear what, if any, impact these developments may have on the statutory accelerated approval pathway or our business, financial condition, results of operations or prospects. Of the large number of biopharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory bodies' approval processes and are commercialized. Even if we eventually complete clinical testing and receive approval from the FDA or applicable foreign agencies for any of our product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. Failure to complete such post-marketing requirements in accordance with the timelines and conditions set forth by the FDA or the applicable foreign regulatory agency could significantly increase costs or delay, limit or ultimately restrict **or curtail** the commercialization of the product candidate. The FDA or the applicable foreign regulatory agency also may approve one or more of our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects. We have chosen to prioritize development of our individualized immunotherapy candidate, GRANITE, and our off- the- shelf immunotherapy candidate, SLATE. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on other product candidates or indications for which there may be a greater likelihood of success or that may be more profitable. In our cancer programs, we **have** strategically determined initially to focus solely on the development of individualized cancer immunotherapy candidates (including our " off- the- shelf " immunotherapy candidate) rather than **to** pursue other types of immunotherapies based, in part, on the significant resources required to develop and manufacture immunotherapies. As a result, we may initially have foregone, and we may continue to forego, other potentially more profitable therapy indications or those with a greater likelihood of success. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the oncology or biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights. If we are unable to obtain regulatory approval for use of our tumor- specific immunotherapy candidates, GRANITE and SLATE, as a first- and second- line therapy, our commercial opportunity and profitability may be limited. Cancer therapies for advanced / metastatic cancers are sometimes characterized as first- line, second- line or third- line, and the FDA often approves new systemic therapies initially only for third- line use. When cancer is detected early enough, surgery plus first- line systemic therapy is sometimes adequate to cure the cancer. Whenever first- line therapy (usually chemotherapy, hormone therapy, radiotherapy, surgery or a combination of these) proves unsuccessful, second- line therapy may be administered. Second- line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor- targeted small molecules or a combination of these. Third- line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies and new technologies such as adoptive cell therapies. Traditionally, novel oncology therapeutics are developed and approved in late (third) line therapy of cancer patients. Such clinical programs carry risk of failure because patients are often quite frail, with effects of multiple rounds of prior therapy weakening bone marrow, immune systems and general fitness. Immunotherapy, such as checkpoint inhibitors, has generally been shown to be more effective when used in earlier lines of therapy, with the prospect of very durable responses in some patients; and there is a trend towards earlier use of these agents, avoiding in particular cytotoxic chemotherapy agents, which carry substantial toxicity and very little prospect of long- term responses. Our tumor-

specific immunotherapy clinical development program also aims to study our products in early stages of cancer treatment (referred to as adjuvant therapy), which carry a higher safety bar, and often a greater expectation of efficacy over control arms. Such studies may thus be relatively large and slow to achieve maturity. There are new tools available to stratify cancer patients for risk of recurrence or progression, such as liquid biopsies that measure the amount of circulating tumor- derived DNA. We will utilize these tools to attempt to expedite clinical trials in early- stage cancer patients by focusing upon patients at above-average risk of disease recurrence or progression, which events are typical endpoints in clinical trials. The development of liquid biopsies is at an early stage, however, and these tools may prove to carry low utility and thus render early- stage cancer trials slow, necessarily large and expensive. The safety of our tumor- specific immunotherapy product candidates in combination with checkpoint inhibitors in early lines of therapy may also prove to be unacceptable. We expect to seek approval of our tumor-specific immunotherapy product candidates as a first- line therapy wherever possible, but also as a late- line therapy where appropriate, and potentially as adjuvant therapy. There is no guarantee that our product candidates, even if approved in late- line therapy, would be approved for second- line or first- line or adjuvant therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for first- line or adjuvant therapy. While our SLATE product is designed to be readily available (off- the- shelf), GRANITE may initially take approximately 14 to 18 weeks post- sequencing to be manufactured and released for human use, and this long timeline demands that either patients are consented and entered into our trials when they start a prior line of therapy, and start our therapy upon disease progression, or we initiate treatment in patients who have entered the maintenance phase of their original line of treatment. For example, we might enroll newly diagnosed patients who are due to receive front- line chemotherapy and then start their therapy with our immunotherapy product candidate as second- line treatment when they progress upon front- line chemotherapy or fail to tolerate it. This carries the risk of time delays or drop- out, i. e., patients may not progress after first- line chemotherapy for a long time, or they may decide not to receive an immunotherapy product candidate we have manufactured for them, at our expense. Alternatively, we may treat first- line patients once they have completed their initial treatment and have not progressed (called maintenance therapy) — this renders efficacy harder to interpret versus simple treatment studies (any objective response cannot clearly be attributed to our products) and may be complicated by standard of care treatments, which may necessarily be continued alongside our immunotherapy candidates, further confounding interpretation of efficacy. Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive first-, second- or third- line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research, and may prove to be incorrect. Regulatory authorities also may establish narrower definitions around when a patient is ineligible for other treatments than we have used in our projections, and that would reduce the size of the patient population eligible for our product candidates. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients 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, we anticipate that only a fraction of colorectal cancer patients will be predicted to have a high enough probability of TSNA presence to merit their inclusion into our program. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first- line or second- line therapy. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. The timely completion of our clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including: • the patient eligibility criteria defined in the protocol; • the size of the patient population required for analysis of the trial' s primary endpoints; • the proximity of patients to trial sites; • the design of the trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • clinical trial investigators' willingness to enroll patients during a public health crisis ~~, such as the COVID- 19 pandemic~~ ; • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating; and • our ability to obtain and maintain patient consents. Our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and such competition may reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. In addition, ~~as~~ we have **historically** faced challenges with patient enrollment and monitoring once on study due to the COVID- 19 pandemic, **and** similar challenges are likely in case of a resurgence of the COVID- 19 pandemic or if another such public health crisis were to occur. Further, the targeting of TSNA may result in unforeseen events, including harming healthy tissues in humans. As a result, it is possible that safety concerns could negatively affect patient enrollment among the patient populations that we intend to treat. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. As with most biological products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. While we have now completed the Phase 1 portions, and we are in the Phase 2 portions, of our clinical

trials of GRANITE and SLATE, we do not yet have a comprehensive understanding of their risks, and it is likely that there will be side effects associated with their use in increasing numbers of patients in Phase 2 and beyond. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. Our other product candidates present similar risks, the severity of which is difficult to predict. If unacceptable side effects arise in the development of our product candidates, we, the FDA, or comparable foreign regulatory authorities, the IRBs **or Ethics Committees** at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, even if we successfully advance one **or more** of our product candidates through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi- year period. There have been several reported cases of severe thrombosis with thrombocytopenia occurring post- vaccination in individuals who received adenovirus- based vaccines for SARS- CoV- 2, including those administered under EUA. This syndrome has been termed " vaccine- induced prothrombotic immune thrombocytopenia (VIPIT) " or " vaccine- induced immune thrombotic thrombocytopenia (VITT) " but is now termed " thrombosis with thrombocytopenia syndrome (TTS) " by the Centers for Disease Control and Prevention (CDC) and the FDA. The syndrome appears to be autoimmune in nature and is associated with autoantibodies to a specific platelet- associated antigen. To date, no patients receiving our adenoviral vaccine candidate against SARS- CoV- 2, CORAL, have been known to develop TTS, nor have we observed it in our cancer programs where our adenoviral vaccines are used in conjunction with checkpoint inhibitors (e. g., anti- PD1 antibody), which themselves can be associated with autoimmune toxicities; but we cannot be certain that this or similar complications will not arise. If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may vary, suspend or revoke their approval of the product; • we may be required to recall a product or change the way such product is administered to patients; • additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof; • regulatory authorities may require the addition of labeling statements, such as a " black box " warning or a contraindication; • we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS), or similar risk management measures, or create a Medication Guide outlining the risks of such side effects for distribution to patients; • we could be sued and held liable for harm caused to patients; • the product may become less competitive; and • our reputation may suffer. Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially adversely affect our results of operations and business. In addition, if one or more of our product candidates or our TSNA- directed immunotherapy approach generally prove to be unsafe, our entire technology platform and pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Even if one of our product candidates obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success. Even if one of our product candidates receives FDA or other regulatory approvals, the commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including: • the clinical indications for which the product is approved and patient demand for approved products that treat those indications; • the safety and efficacy of our product as compared to other available therapies; • the time required for manufacture and release of our individualized immunotherapy products; • acceptance by physicians, operators of hospitals and clinics and patients of the product as a safe and effective treatment; • physician and patient willingness to adopt a new therapy for appropriate patients versus other available therapies for a particular indication; • proper training and administration of our product candidates by physicians and medical staff; • patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen; • the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third- party payers, physicians and patients; • the prevalence and severity of side effects; • limitations or warnings contained in the FDA or foreign regulatory authorities- approved labeling for our products; • the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our products as a solution; • any FDA or foreign regulatory authorities' requirement for a REMS or similar risk management measures; • the effectiveness of our sales, marketing and distribution efforts; • adverse publicity about our products or favorable publicity about competitive products; and • potential product liability claims. We cannot assure you that our current or future product candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations. We currently perform most of the manufacturing of our product candidates internally and rely on qualified third parties to supply some components of our product candidates. Our inability to manufacture sufficient quantities of any of our current or future product candidates, or the loss of our

third- party suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially adversely affect our business. Manufacturing is a vital component of our immunotherapy approach, and we have invested significantly in our manufacturing ~~facility~~ **facilities** . To ensure timely and consistent product supply assurance to our patients, we previously used a hybrid product supply approach whereby certain elements of our product candidates were manufactured internally at our manufacturing facilities in Pleasanton, California, and other elements were manufactured at qualified third- party contract manufacturing organizations (CMOs). All internal and third- party contract manufacturing is performed under cGMP or similar guidelines. We have since internalized most of the manufacturing steps to optimize cost and production time and establish full control over intellectual property and product quality. We will need to continue to scale up our manufacturing operations, as we continue to build the infrastructure and improve the capability internally to manufacture all supplies needed for our product candidates or the materials necessary to produce them for use in the conduct of our preclinical studies or clinical trials. We currently lack the internal resources and the capability to manufacture certain elements of our product candidates on a late- clinical or commercial scale. Accordingly, we have made, and will be required to continue to make, significant investments in our manufacturing facility and processing in the future, and our efforts to scale our manufacturing operations may not succeed. Our facilities and the facilities used by our CMOs to manufacture our product candidates are subject to various regulatory requirements and may be subject to inspection by the FDA or other regulatory authorities. We do not control the manufacturing process at our CMOs and are completely dependent on them for compliance with current regulatory requirements. If we or our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on our or their manufacturing facilities for the manufacture of elements of our product candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds our facilities or those of our CMOs inadequate for the manufacture of our product candidates, or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. Additionally, even if one of our product candidates receives regulatory approval, successful commercialization depends on our ability to effectively scale up our in-house manufacturing capabilities and those of our manufacturing partners and contractors. Although we have a dedicated manufacturing facility in Pleasanton, we do not have sufficient manufacturing infrastructure to support a global roll- out of our product candidates on our own. We may not be able to timely and effectively produce our product candidates, if approved, in adequate quantities to address global demand. We have not previously had a commercial launch of any product, and we cannot guarantee that we will be able to meet any of the related challenges and requirements in a timely manner or at all. Finally, we and our CMOs may experience manufacturing and raw material sourcing difficulties due to resource constraints, as a result of labor disputes or unstable political environments, or due to the impact of a public health crisis ~~such as the COVID- 19 pandemic~~ . If we or our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized. We depend on third-party suppliers for key materials used in our manufacturing processes, and the loss of these third- party suppliers or their inability to supply us with adequate materials could harm our business. We rely on third- party suppliers for certain materials required for the production of our individualized immunotherapy candidate. Our dependence on these third- party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our larger competitors. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business. We rely, and intend to continue to rely, on third parties in the conduct of all of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates. We currently do not have the ability to independently conduct preclinical studies that comply with good laboratory practice (GLP) regulatory requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as good clinical practice (GCP) requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP- compliant preclinical studies and GCP- compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our GCP- compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GLP- compliant preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in

accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. Further, under certain circumstances, these third parties may terminate their agreements with us upon as little as 10 days' prior written notice. Some of these agreements may also be terminated with immediate effect by such third parties under certain other circumstances, including our insolvency. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLPs / GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates could be harmed, our costs could increase, and our ability to generate revenues could be delayed. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA or foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA' s or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times, and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. ~~Separately~~ **Additionally** , in response to the COVID- 19 pandemic, ~~in March 2020,~~ the FDA ~~announced its intention to postpone most inspections of foreign manufacturing facilities,~~ and ~~on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on- site inspections of domestic manufacturing facilities subject to a risk- based prioritization system. The FDA utilized this risk- based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plan to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may~~ **many** ~~request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID- 19 pandemic and has also indicated that it intends to utilize remote~~ regulatory ~~assessments and other alternative tools beyond the COVID- 19 pandemic. Regulatory~~ authorities outside the United States ~~have~~ adopted ~~similar~~ restrictions **and postponed inspections** ~~or other policy measures in response to the COVID- 19 pandemic~~ . If a prolonged government shutdown occurs, or if global health concerns ~~continue to~~ **once again** prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We face significant competition in an environment of rapid technological and scientific change, and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete. The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. We compete with a variety of multinational biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes that may compete with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that enter the market. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of diseases and other conditions for which we may try to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and antibody and immunoregulatory therapeutics fields. We believe that, while our discovery platform, its associated intellectual property and our scientific and technical know- how give us a competitive advantage in this space, competition from many sources remains. Our competitors include larger and better funded biopharmaceutical, biotechnological and therapeutics companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions. Our success will partially depend on our ability to develop and protect therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products that are safer, more effective, or less expensive than the therapeutics we develop. For example, if either of our

GRANITE or SLATE vaccine candidates is approved, it will compete with a range of therapeutic treatments that are either in development or currently marketed, of which there are many. Such marketed therapies range from immune checkpoint inhibitors such as Bristol- Myers Squibb Company' s OPDIVO and YERVOY, Merck & Co., Inc.' s KEYTRUDA, AstraZeneca' s IMFINZI, and Genentech, Inc.' s TECENTRIQ, T cell engager immunotherapies such as Amgen, Inc.' s BLINCYTO, and multi- kinase inhibitors such as Bayer' s STIVARGA. The most common therapeutic treatments for common solid tumors are chemotherapeutic compounds, radiation therapy, targeted therapies and now immunotherapies. In addition, numerous compounds are in clinical development for cancer treatment. The clinical development pipeline for cancer treatments includes small molecules, antibodies and immunotherapies from a variety of groups, including in the neoantigen space, the bispecific antibody space and engineered cell therapy and T cell receptor (TCR) space. Many of these companies are well- capitalized and, in contrast to us, have significant clinical experience. **In addition, if our CORAL vaccine candidate is approved, it will compete with a range of therapeutic treatments, including marketed therapies such as Pfizer and BioNTech' s COMIRNATY and in- development treatments such as Replicate Biosciences' self- replicating RNA treatments for infectious diseases.** Despite funding provided to us to date, many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. If any competitors are successful in producing more efficacious products or if any competitors are able to manufacture and distribute competitive products with greater efficiency there may be a diversion of potential governmental and other funding away from us and toward such other parties. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities, private health insurers, and other third- party payors provide coverage, adequate reimbursement levels and implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The availability of coverage and adequacy of reimbursement by managed care plans, governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third- party payors are essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates that receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by third- party payors will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult due to general price sensitivity associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third- party payor not to cover or separately reimburse for our products, or procedures using our products, could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our product candidates, by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union Member States or elsewhere will be available for our product candidates or procedures using our product candidates, or any product that we may develop, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. Third- party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third- party therapeutics may not necessarily inform the price for our product candidates. These third- party payors may deny or revoke the reimbursement status of our product candidates, if approved. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates. There is significant uncertainty related to the insurance coverage and reimbursement of newly- approved products, especially novel products like our immunotherapy product candidates. No regulatory authority has granted approval for a tumor- specific cancer immunotherapy based on a vaccine approach, and there is no model for reimbursement of this type of product. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. No uniform policy for coverage and reimbursement for products exists among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that may require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that future changes in these rules and regulations are likely. In addition, companion

diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products, and, as a result, they may not cover or provide adequate payment for our product candidates. For example, the recently- enacted Inflation Reduction Act directs the Secretary to negotiate maximum fair prices for certain Medicare drugs. The law also requires manufacturers to pay a rebate if the price of a Medicare Part B or Part D drug increases at a rate that exceeds inflation and redesigns the Medicare Part D benefit in a way that potentially obligates manufacturers to increased discounts on Part D utilization. **Additionally, some state legislatures have established Prescription Drug Affordability Boards (PDABs), which in certain cases are authorized to set upper payment limits for drugs administered or dispensed in the state.** We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. If we are unable to support demand for our existing or future services, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage the evolution of our EDGE ™ platform, our business could suffer. As the demand for our individualized and off- the- shelf vaccine- based immunotherapy candidates increases with our clinical trial needs, we will need to continue to increase our workflow capacity for sample intake and general process improvements, expand our internal quality assurance program, and apply our EDGE ™ platform at a larger scale within expected turnaround times. We will need additional certified laboratory scientists and technicians and other scientific and technical personnel to process higher volumes of tumor biopsies. Portions of our process are not automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take several months or more to procure, set up, and validate, and increase our software and computing capacity to meet increased volume. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory facilities to accommodate such required expansion. As we progress ~~into~~ **through** clinical development and expand our manufacturing capabilities, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher service costs, declining service quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our services and could damage our reputation and the prospects for our business. We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and foreign jurisdictions, if approved, or generate product revenue. We currently do not have a marketing or sales organization. In order to commercialize our product candidates, if approved, in the United States and foreign jurisdictions, we will need to build our marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our product candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of them. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing our current or any future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses. We will need to increase the size of our organization, and we may experience difficulties in managing growth. As of December 31, ~~2022~~ **2023** , we had ~~233~~ **231** full-time employees. As our clinical trials progress and we get closer to any potential regulatory approvals, we will need to expand our managerial, regulatory, clinical science, development operations, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our product candidates or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support our future needs. Our need to effectively execute on our growth strategy requires that we: • manage our preclinical studies and clinical trials effectively; • identify, recruit, retain, incentivize and integrate additional employees, including sales personnel; •

manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and • continue to improve our operational, financial and management controls, reports systems and procedures. If we fail to attract and retain senior management and key scientific personnel, our business may be materially adversely affected. Our success depends in part on our continued ability to attract, retain and motivate highly- qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our President and Chief Executive Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our products, initiation or completion of our planned clinical trials or the commercialization of our current or any future product candidates. Competition for qualified personnel in the biotechnology and biopharmaceutical fields is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output **. Further, the reduction in workforce we announced in February 2024 may also make retention of our current personnel both more important and more challenging. The workforce reduction resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel** . If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates. We face an inherent risk of product liability as a result of the planned clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our current or future product candidates; • injury to our reputation; • withdrawal of clinical trial participants; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; and • the inability to commercialize our current or any future product candidates. Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our current or any future product candidates we develop. We currently carry product liability insurance covering our clinical trials in the amount of $ 10. 0 million in the aggregate. Nonetheless, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all. Our strategic collaborations, including those with Gilead and with 2seventy as well as any future arrangements that we may enter into, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of such collaborations and adversely affect our ability to develop and commercialize our product candidates. In February 2021, we ~~announced that we had~~ entered into a collaboration, option and license agreement with Gilead to research and develop a vaccine for HIV. Under the terms of the agreement, Gilead is responsible for conducting the Phase 1 study and, if it exercises its exclusive option, will develop and commercialize the HIV- specific therapeutic vaccine beyond Phase 1. In such case, subject to certain clinical, regulatory and commercial milestones being achieved, we would be eligible to receive up to an additional $ 725. 0 million, as well as certain royalties on net sales upon commercialization. Separately, in August 2018, we entered into a strategic collaboration with 2seventy to utilize our EDGE ™ platform to identify and validate tumor- specific targets and provide TCRs directed to 10 selected targets for use in 2seventy' s cell therapy products. Under that collaboration, we are entitled to receive up to an aggregate of $ 1. 2 billion in development, regulatory and commercial milestones and tiered single digit royalties on sales of 2seventy' s cell therapy products utilizing the TCRs we develop directed at the targets we discovered. Apart from these strategic collaborations, in the future, we may seek to enter into additional collaboration arrangements for the development or commercialization of certain of our product candidates, depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. To the extent that we decide to enter into collaboration agreements in the future, we may face significant competition in seeking appropriate collaborators. Moreover, all such collaboration arrangements are complex and time- consuming to negotiate, document, implement and maintain, as well as challenging to manage. We may not be successful in our efforts with Gilead or 2seventy, and we may never receive any of the payments contemplated in those collaboration arrangements. Further, we may be unable to prudently manage these collaborations or enter into new ones. The terms of any new collaborations or other arrangements that we may establish may not

be favorable to us. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that: • collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations; • collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates; • a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise perform satisfactorily in carrying out these activities; • we could grant exclusive rights to our collaborators that would prevent us from collaborating with others; • collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; • disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources; • collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates; • collaborators may own or co-own intellectual property covering products that result from our collaboration with them, and, in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; • disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and • a collaborator' s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings. If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: • increased operating expenses and cash requirements; • the assumption of additional indebtedness or contingent liabilities; • the issuance of our equity securities; • assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel; • the diversion of our management' s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition; • retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and • our inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. **Unfavorable global economic conditions could adversely affect our business, financial condition, or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and financial markets. If the conditions in the general economy deteriorate, including as a result of supply chain disruptions, regional conflicts around the world, recent instability in the banking sector, inflation and market volatility, rising interest rates, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, cybersecurity events, the ongoing labor shortage, or otherwise, our business, financial condition, and operating results could be adversely affected. Among other challenges, a severe or prolonged economic downturn, could adversely impact our suppliers' ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition, and results of operations.** We, or the third parties upon whom we depend, may be adversely affected by ~~risks beyond our control, such as~~ natural disasters **, public health crises** , political crises, acts of terrorism, war or other catastrophic events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. We, our suppliers and third- party service providers are vulnerable to damage from natural disasters, including but not limited to earthquakes, fires or floods, power loss, communications failures, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war, political instability or other conflict and similar events. If any disaster were to occur, our ability to operate our business at any of our facilities could be seriously, or potentially completely, impaired. Our corporate headquarters and certain of our other facilities, including our manufacturing facility, are located in the San Francisco Bay Area, which in the past has experienced both severe earthquakes and wildfires. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. For example, if a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or other facilities, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. ~~In addition, in late February 2022, Russian military forces launched significant military action against Ukraine. In response, many countries and organizations implemented new, stricter sanctions against officials, individuals, regions, and industries in Russia and Belarus. These and other actions related to Russia' s invasion of Ukraine have~~

~~also been a major contributing factor to high inflation as well as putting significant downward pressure on economic growth. Apart from the tragic loss of life and human suffering, the war in Ukraine has had, and likely will continue to have, an adverse effect on the global economy and political situation.~~ If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or other facilities, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. **In addition, our operations expose us to risks associated with public health crises, such as pandemics and epidemics, which could harm our business and cause our operating results to suffer. Further, acts of war, terrorism, labor activism or unrest and other geopolitical unrest, including ongoing conflicts in Ukraine and Israel, could cause disruptions in our business, the businesses of our partners or the economy as a whole.** Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business. We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition. We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, including our laboratory information management system and our EDGE ™ platform. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and **certain** personal **information, including health- related** information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established **commercially reasonable** physical, ~~electronic~~ **technical** and organizational measures **designed** to safeguard and secure our systems **from potential** ~~to prevent a~~ data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information **, including confidential information** . We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our **systems and infrastructure and to our** confidential information **stored thereon** . Our internal information technology systems and infrastructure, and those of our current and any future collaborators, **our third- party CROs and other** contractors and consultants **,** and other third parties on which we rely, are vulnerable to attack and ~~damage~~ **potential compromise** from computer viruses, and malware (e. g., ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, cyber- attacks or cyber- intrusions over the ~~Internet~~ **internet , phishing campaigns** , attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption or data loss, particularly through cyber- attacks or cyber intrusion, including by computer hackers, 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. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the ~~loss~~ **compromise** of confidential information or other intellectual property. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, either full- time or on a hybrid basis, which may create additional opportunities for ~~cybercriminals~~ **bad actors** to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, **or otherwise compromise** systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures **before such techniques are deployed** . We may also experience security breaches that may remain undetected for an extended period **, which can substantially increase the potential for a material adverse impact resulting from the breach** . Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We have experienced phishing attacks in the past resulting in a security breach of our information technology systems, and we may be a target of phishing attacks or other cyber- attacks in the future. **As the cyber- threat landscape evolves, these attacks are growing in frequency, sophistication, and intensity, and are becoming increasingly difficult to detect. Bad actors are increasingly sophisticated in using techniques and tools- including artificial intelligence- that circumvent security controls, evade detection and remove forensic evidence of attempted or actual cyber- attacks. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, which can be deployed through various means, including the software supply chain, e- mail, malicious websites and / or the use of social engineering / phishing.** Any significant system failure, accident or security breach could have a material adverse effect on our business, financial condition and results of operations. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release

of ~~personally~~ -- **personal** ~~identifiable~~ information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal ~~and~~ **,** state **and foreign** privacy and security laws, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. **Applicable data privacy and security obligations may also require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences, including litigation from individuals with private rights of action.** We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition. Further, **while we maintain cybersecurity insurance,** our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption ~~or~~ **,** breach of our systems **, loss or other compromise of our critical or sensitive data. Cyber- attackers are also increasingly exploiting vulnerabilities in commercially available software from shared or open- source code. We rely on third party commercial software that have had and may have such vulnerabilities, but as use of open- source code is frequently not disclosed, our ability to fully assess this risk to our systems is limited. Although we develop and maintain systems and controls designed to prevent these events from occurring and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes are costly and require ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, we cannot guarantee that our or our service providers' security measures will be sufficient to prevent data loss and other security breaches. Despite our efforts, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber- attacks or security breaches that could adversely affect our business. Regulations continue to change as regulators worldwide consider and implement new rules. For example, the SEC has adopted additional disclosure rules regarding cyber security risk management, strategy, governance and incident reporting by public companies, where failure to report cybersecurity incidents may result in regulatory investigations leading to consent orders that may require additional compliance obligations and / or injunctions, fines and other penalties. Such actions could result in significant legal and financial exposure and reputational damages that could have a material adverse effect on our business, financial condition, results of operations and prospects** . Our business is subject to complex and evolving laws and regulations regarding privacy, data protection and other matters relating to information collection. There are numerous state, federal and **foreign** ~~non- U. S.~~ laws, regulations, decisions, and directives regarding privacy and the collection, storage, transmission, use, processing, disclosure and protection of different types of ~~personal data and~~ personal information and other personal, customer, or other data, the scope of which is continually evolving and subject to differing interpretations. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions **, criminal prosecution** , claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business. In the United States, although we currently are not subject to the privacy or security regulations implementing HIPAA, many of the persons and organizations with which we interact are subject to those regulations and we have to expend resources to understand their obligations, adjust contractual relationships in light of those obligations, or otherwise modify our business practices. Congress has considered expanding the scope of the HIPAA privacy and security regulations and we may in the future ourselves become subject to them or similar regulations, which would require us to make additional expenditures and create additional liability risks. At the state level, many U. S. states in which we operate have laws that protect the privacy and security of personal information, and other states have proposed privacy legislation that may **be** more stringent or broader in scope, or offer greater individual rights, than the laws to which we currently are subject. This patchwork of evolving privacy ~~law~~ **laws** complicates our compliance efforts, at considerable cost. Even a single state' s privacy regime can be very complicated. For example, the ~~California Confidentiality of Medical Information Act (the " CMIA ")~~ imposes on pharmaceutical companies strict data privacy and security requirements and obligations with respect to **medical** ~~the personal health~~ information ~~of California residents~~ and authorizes administrative fines and civil penalties of up to $ 25, 000 for willful violations and up to $ 250, 000 if the violation is for purposes of financial gain, as well as criminal fines. **The CMIA also provide individuals as a private right of action, which may be brought as a class action for alleged violation.** In parallel, the ~~California Consumer Privacy Act of 2018 (the " CCPA ")~~ , which was substantially amended in 2020 pursuant to the California Privacy Rights Act ~~(the " CPRA ")~~ , which generally went into effect on January 1, 2023, generally requires us to provide notice to California residents **including employees and business contacts** regarding the personal information we collect, use and share and to honor such residents' privacy rights, including the right to opt out of the sale of their personal information **or the use of their personal information for online targeted advertising** . The CCPA provides for civil penalties for violations, as well as a private right of action for data security breaches that result in the compromise of ~~sensitive~~ personal information. California' s **willingness** ~~aggressive steps~~ to protect consumer privacy ~~have~~ **has** been followed by ~~similar actions in~~ other states **enacting consumer privacy laws** , including **Colorado, Connecticut, Delaware, Indiana, Iowa, Montana, New Jersey, Oregon, Tennessee, Texas, Utah, and** Virginia ~~, Colorado, Utah and Connecticut~~ , all of which have enacted **consumer privacy** ~~CCPA / CPRA- like~~ laws to provide their respective residents with similar rights **to those afforded by the CCPA** , and have been proposed in other states and at the federal level, reflecting a trend

toward more stringent privacy legislation in the United States. **In addition, both Nevada and Washington State recently enacted privacy laws specifically applicable to consumer health information, which, with limited exceptions, prohibits sharing personally identifiable health data without consent. The Washington State law, also known as the My Health My Data Act, will be fully effective in March 2024 and is enforceable by individual consumers, including through class actions, as well as the Washington Attorney General.** The effects on our business of this rapidly growing body of privacy and data protection laws are ~~potentially~~ significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply. In the **EA** ~~European Union~~, the ~~General Data Protection Regulation (~~GDPR ~~)~~ went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. The GDPR has increased our obligations, for example, by imposing higher standards when obtaining consent **where necessary** from individuals to process their personal data, requiring more robust disclosures to individuals, strengthening individual data rights, shortening timelines for data breach notifications, limiting retention periods and secondary use of information, increasing requirements pertaining to health data as well as pseudonymized (i. e., key- coded) data, and imposing additional obligations when we contract **with** third- party processors in connection with the processing of personal data. The GDPR also regulates transfers of personal data subject to the GDPR to third countries that have not been found **by the European Commission** to provide adequate protection to such personal data; in July 2020, the Court of Justice of the European Union (~~"~~ **"** CJEU ~~"~~ **"**) limited how organizations could lawfully transfer personal data from the EU / EEA to the U. S. by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions ~~on~~ **for** the use of standard contractual clauses (**"** SCCs **"**). In ~~March~~ **July** ~~2022~~ **2023**, the U. S. and EU **implemented** ~~announced a new regulatory regime intended to replace~~ the ~~invalidated regulations; however, this new~~ EU- U. S. Data Privacy Framework ~~has not been implemented beyond~~ **(" DPF") replacing the invalidated Privacy Shield. Companies that self- certify to the DPF** ~~an~~ **can** ~~executive order signed by President Biden on~~ **now use this mechanism to transfer personal data from the EU / EEA to the U. S. and from Switzerland to the U. S. The UK Extension to the EU- U. S. Data Privacy Framework entered into force in** October ~~7, 2022~~ **2023** ~~on Enhancing Safeguards~~ **, allowing certifying entities to transfer personal data from the UK to the U. S. At the moment it is unclear whether the anticipated legal challenges against the DPF, which may be similar to the challenge that led to the invalidation of the Privacy Shield, would be successful. It is further unclear how long it would take** for **any challenges** ~~United States Signals Intelligence Activities. European court and regulatory decisions subsequent~~ to **be resolved** ~~the CJEU decision of July 2020 have taken a restrictive approach to international data transfers~~. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and / or **take** ~~start taking~~ enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. ~~From~~ **Since** January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom GDPR (**"** UK GDPR **"**), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR (i. e., fines up to the greater of € 20 million (£ 17. 5 million) or 4 % of global turnover). As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure, or perceived failure, by us to comply with or make effective modifications to our policies, or to comply with any federal, state or ~~international~~ **foreign** privacy, data- retention or data- protection- related laws, regulations, orders or industry self- regulatory principles could result in proceedings or actions against us by governmental entities or others, a loss of customer confidence, damage to our brand and reputation and a loss of customers, any of which could have an adverse effect on our business. In addition, various federal, state and foreign legislative or regulatory bodies may enact new or additional laws and regulations concerning privacy, data- retention and data- protection issues, including laws or regulations mandating disclosure to domestic or international law enforcement bodies, which could adversely impact our business or our reputation with customers. For example, some countries have adopted laws mandating that some personal information regarding customers in their country be maintained solely in their country. Having to maintain local data centers and redesign product, service and business operations to limit personal information processing to within individual countries could increase our operating costs significantly. Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations. We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U. S. federal and state healthcare fraud and abuse, data privacy laws and other similar non- U. S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in 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. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other U. S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non- compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Our business involves the use of hazardous materials, and we and our third- party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business. Our research and development activities and our third- party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and product candidates and other hazardous compounds. We and any third- party manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our third- party manufacturers' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third- party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third- party facilities. In such an event, we may be held liable for any resulting damages; such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses that we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations and financial condition. ~~Our business may be materially adversely affected by a public health crisis such as the ongoing COVID- 19 pandemic, including a resurgence of the COVID- 19 pandemic or localized outbreaks in certain parts of the world. While the COVID- 19 pandemic did not materially adversely affect our business operations during the year ended December 31, 2022, economic and health conditions in the United States and across most of the globe have changed considerably since the pandemic began. In particular, supply chain disruptions have become a concern for many businesses, particularly if critical supplies are sourced from China or other regions where extended lock- downs remain a real possibility. The COVID- 19 pandemic also caused significant volatility in the U. S. and international markets and was a contributing factor to high inflation and extended economic downturn. We are subject to inflationary pressures on employee wages, salaries, and the cost of various goods and services that can negatively impact our financial results. We have experienced minor delays in delivery of various products related to our manufacturing processes and in some cases have had to identify new suppliers, which at times resulted in increased costs. While none of the disruptions of our supply chain to date have been material, we cannot exclude the possibility that further supply chain disruptions due to a resurgence of the COVID- 19 pandemic, even if limited to localized outbreaks in certain parts of the world, could have a material adverse effect on our business, and the extent to which these issues will impact our results remains uncertain. Moreover, the emergence of any new pandemic or similar public health crisis would subject our business to risks similar to those of the COVID- 19 pandemic. In addition to the risk of such supply chain disruptions, as a result of the COVID- 19 pandemic, including a resurgence or localized outbreaks in certain parts of the world, we may also experience disruptions that could severely impact our business, preclinical studies and clinical trials, including: • We are conducting a number of clinical trials for product candidates in geographies that have been heavily affected by the COVID- 19 pandemic. While the availability of first- generation vaccines in the United States (and other countries) have greatly improved the outlook for the pandemic, we believe that the emergence of variants of concern and / or the potential waning of the immune protection offered by existing vaccines has the potential to lead to prolonging the effects of the pandemic, which could in turn have an impact on various aspects of our clinical trials. For example, with respect to clinical trials for our tumor- specific immunotherapy product candidates, investigators may not want to screen or treat cancer patients with our experimental vaccine~~

~~and potentially expose them to the novel coronavirus during additional clinic visits. Other potential impacts of the COVID- 19 pandemic on our various clinical trials include delays or difficulties in any planned clinical site initiation, including difficulties in obtaining IRB or ethics committee approvals, recruiting clinical site investigators and clinical site staff, delays or difficulties in enrolling patients, interruption of planned key clinical trial activities, such as clinical trial site data monitoring due to diversion of resources at clinical sites or limitation on travel imposed by federal or state governments. This may impact the integrity of subject data. • While chimpanzee- based adenoviral (ChAd) vaccines have not yet been approved in the US, there is a risk that patient candidates to our GRANITE or SLATE vaccine candidates may become ineligible due to pre- existing neutralizing antibodies to ChAd vaccines, for example following participation in SARS- CoV- 2 clinical trials using such vaccines. This in turn could slow down recruitment to our clinical trials, especially if we were to consider expanding our trials in the EU, and, ultimately, if these ChAd vaccines against SARS- CoV- 2 are proven effective and become widely available in the general population, may render our vaccination approach unsuitable for many cancer patients. Similarly, patients who have been previously vaccinated with a mRNA- based vaccine may be reluctant to receive our samRNA vaccines or may have contraindications, such as allergic reaction to their SARS- CoV- 2, mRNA- based vaccines. • Our increased reliance on personnel working from home, a shift that began with the COVID- 19 pandemic but has become the established norm, may negatively impact productivity or disrupt, delay or otherwise adversely impact our business. In addition, this could increase our cyber- security risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and important agencies and contractors. • The FDA and comparable foreign regulatory agencies may experience operational interruptions or delays, which may impact timelines for regulatory submission, trial initiation and regulatory approval. The COVID- 19 outbreak has become less of a direct threat to public health in countries that have achieved relatively high vaccination rates, such as the United States; but, it remains unclear when the pandemic will cease to pose a threat to the global economy, particularly if full global vaccination is not achieved or existing vaccines prove less effective against new variants of the virus. The extent to which the outbreak may impact our business, manufacturing, preclinical development activities, preclinical studies and planned clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the potential for localized outbreaks of COVID- 19 in countries or regions with relatively low vaccination rates, travel restrictions, lock- downs and other actions to contain the outbreak or treat its impact, business closures or business disruptions, and the effectiveness of actions taken to contain and treat the disease.~~ Risks Related to Intellectual Property Our success depends on our ability to protect our intellectual property and our proprietary technologies **and to avoid infringing the rights of others** . Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. We have applied, and we intend to continue applying, for patents covering aspects of our product candidates, proprietary technologies and their uses that we deem appropriate. However, we may not be able to apply for patents on certain aspects of our current or future product candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition. As of December 31, ~~2022~~ **2023** , our solely owned patent portfolio includes pending patent applications and issued patents. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office (USPTO) **and** courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our product candidates, proprietary technologies and their uses by obtaining and defending patents. These risks and uncertainties include the following: • the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; • patent applications may not result in any patents being issued; • patents that may be issued or in- licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage; • our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates; • other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that

overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position; • any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop; • because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses; • an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and • countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates. The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Moreover, the patent prosecution process is also expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, if issued, or the patent rights that we license from others, may be challenged in the courts or patent offices in the United States and abroad. Once granted, patents may remain open to opposition, interference, re- examination, post- grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product or service. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed, or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third- party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel. The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that: • any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our products; • any of our pending patent applications or those of our licensors may issue as patents; • others will not or may not be able to make, use, offer to sell, or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license; • we will be able to successfully commercialize our products, if approved, on a substantial scale before the relevant patents that we own or license expire; • we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license; • we or our licensors were the first to file patent applications for these inventions; • others will not develop similar or alternative technologies that do not infringe the patents we own or license; • any of the patents we own or license will be found to ultimately be valid and enforceable; • any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable products or will provide us with any competitive advantages; • a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed; • we may develop or in- license additional proprietary technologies that are patentable; • the patents of others will not have an adverse effect on our business; • our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we will develop additional proprietary technologies or products that are separately patentable; or • our commercial activities or products will not infringe upon the patents of others. Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we

do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. The lives of our patents may not be sufficient to effectively protect our products and business. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non- provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent life has expired, we may be open to competition. In addition, although upon issuance in the United States a patent' s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we do not have sufficient patent life to protect our product candidates, proprietary technologies and their uses, our business and results of operations will be adversely affected. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We rely on the protection of our trade secrets, including unpatented know- how, technology and other proprietary information. We have taken steps to protect our trade secrets and unpatented know- how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third- party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such a competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs, or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by other companies. The patent protection, prosecution and enforcement for some of our product candidates may be dependent on third parties. We currently are reliant upon licenses of certain patent rights and proprietary technology from third parties that is important or necessary to the development of our technology and products, including technology related to our product candidates. For example, we rely on our license agreements with Arbutus and Genevant for certain lipid nanoparticle- based delivery technologies. These and other licenses we may enter into in the future may not provide adequate rights to use such intellectual property and technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to develop and commercialize our technology and products in fields of use and territories for which we are not granted rights pursuant to such licenses. Licenses to additional third- party technology that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition. In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a

manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know- how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in- license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products. Our licensed European patents and patent applications could be challenged in the recently created Unified Patent Court (UPC) for the European Union, that **was** ~~is expected to be~~ fully ratified in 2023. Under our current license agreements, we may not have the final or sole decision on whether we are able to opt out certain of our in- licensed European patents and patent applications from the ~~recently created Unified Patent Court (~~UPC ~~) for the European Union, that is expected to be fully ratified in 2023~~. Our licensors may decide to not opt out of the UPC, which would subject our in- licensed European patents and patent applications to the jurisdiction of the UPC. Furthermore, even if our licensors decide to opt out of the UPC, we cannot guarantee that our licensors will comply with the legal formalities and requirements for properly opting out of the UPC. Thus, we cannot be certain that our in- licensed European patents and patent applications will not fall under the jurisdiction of the UPC. Under the UPC, a single European patent would be valid and enforceable in numerous European countries. A challenge to the validity of a European patent under the UPC, if successful, could result in a loss of patent protection in numerous European countries which could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Our current licenses impose, and our future licenses likely will impose, various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights and could prevent us from developing and commercializing our product candidates and proprietary technologies. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any current or future licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor' s rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. Litigation or other proceedings or third- party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products. Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexaminations, inter partes review proceedings and post- grant review proceedings before the USPTO and / or corresponding foreign patent offices. Numerous third- party U. S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. 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 manufacture of our product candidates ~~. For example, we are aware of and have timely opposed EP Patent 2569633, expiring in May 2031 (absent any patent term adjustments or extensions), directed to certain methods of identifying and using neoantigens. EP Patent 2569633 is currently validated in Great Britain, France, Germany, Netherlands, Italy, Ireland, Spain and Switzerland. Our opposition was filed in our name on November 7, 2016 by Vossius & Partner. Four other parties also filed oppositions to the patent within the required timeframe. The Opposition Division of the European Patent Office (EPO), held opposition hearings on October 15 and 16, 2018, and determined that EP Patent 2569633 does not meet the requirements of the European Patent Convention (EPC) and consequently, revoked the patent. We received notice in April 2019 that EP Patent 2569633 patentees and licensors filed their appeal to the Opposition Division' s decision, and we, along with other opposers, filed responses in August 2019. Opponent Christian Müller withdrew his opposition in May 2020, but the appeal proceedings were to be continued between the remaining parties. The EPO scheduled the oral proceedings for the appeal for September 27 and 28, 2022. However, on August 22, 2022, Appellant filed for withdrawal of their appeal and the oral proceedings were subsequently cancelled. The Opposition Division' s decision revoking EP Patent 2569633 is thus final~~. Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies, products, or product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s

pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates. As the biotechnology industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of, and patents issued to, third parties. Patent applications in the United States and elsewhere are typically published approximately eighteen (18) months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U. S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third- party patents that may be infringed by commercialization of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third- party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could: • result in costly litigation; • divert the time and attention of our technical personnel and management; • cause development delays; • prevent us from commercializing our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law; • require us to develop non- infringing technology, which may not be possible on a cost- effective basis; • require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property; • require us to pay the attorney' s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and / or • require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all. Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent any of our immunotherapy candidates from being marketed. Any patent- related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market the affected immunotherapy candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins, and the rights may be non- exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our immunotherapy candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court. Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in- license is not valid, is unenforceable and / or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and / or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a

misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. For example, third parties may petition the USPTO for post- grant review within nine (9) months of our patent' s issuance date. Further, after the USPTO period for filing post- grant review has expired, third parties may file a petition for inter partes review on certain grounds. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex- U. S. patent offices and may result in the revocation, cancellation, or amendment of any ex- U. S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non- exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in- licenses. We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will depend in part on our ability to acquire, in- license or use these proprietary rights. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment. We have collaborated with U. S. academic institutions and may in the future collaborate with U. S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer. We may fail to comply with any of our obligations under existing or future agreements pursuant to which we license or have otherwise acquired intellectual property rights or technology, which could result in the loss of rights or technology that are material to our business. We are party to various agreements that we depend on to operate our business, including intellectual property rights relating to GRANITE, SLATE and CORAL, in particular, our agreements with Arbutus and Genevant. Our rights to use currently licensed intellectual property or intellectual property to be licensed in the future are subject to the continuation of and our compliance with the terms of these agreements. Disputes may arise regarding our rights to intellectual property licensed to us from a third party, including but not limited to: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the creation or use of intellectual property by us, alone or with our licensors and collaborators; • the scope and duration of our payment obligations; • our rights upon termination of such agreement; and • the scope and duration of exclusivity obligations of each party to the agreement. If disputes over intellectual property and other rights that we have licensed or acquired from third parties

prevent or impair our ability to maintain our current license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under current or future license agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is common in the biotechnology and biopharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or biopharmaceutical companies including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees. If we do not obtain patent term extension for our product candidates, our business may be materially harmed. Depending upon the timing, duration and specifics of FDA marketing approval of GRANITE, SLATE, CORAL or any future immunotherapy candidates, one or more of our U. S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The Hatch- Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations. Changes in patent law in the **United States** ~~U. S.~~ or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Our patent rights may be affected by developments or uncertainty in U. S. or ex- U. S. patent statutes, patent case laws in USPTO rules and regulations or in the rules and regulations of ex- U. S. patent offices. There are a number of changes to the U. S. patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, on September 16, 2011, the Leahy- Smith America Invents Act (Leahy- Smith Act) was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy- Smith Act, the United States transitioned in March 2013 to a " first to file " system in which the first inventor to file a patent application will be entitled to the patent.

Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. This could have a negative impact on some of our intellectual property and could increase uncertainties surrounding obtaining and enforcement or defense of our issued patents. In addition, Congress may pass patent reform legislation that is unfavorable to us. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. ~~Our European patents and patent applications could be challenged in the recently created Unified Patent Court (UPC) for the European Union, that is expected to be fully ratified in 2023. We may decide to opt out our European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Under the UPC, a granted European patent would be valid and enforceable in numerous European countries. Although such patent rights would apply to numerous European countries, a successful challenge to a European patent under the UPC could result in loss of patent protection in numerous European countries. Accordingly, a single proceeding under the UPC addressing the validity and infringement of the European patent could result in loss of patent protection in numerous European countries rather than in each validated country separately as such patents always have been adjudicated. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates~~ We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending all current and future patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and / or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make next generation cancer and infectious disease immunotherapies that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed; • we or our licensors or future collaborators might not have been the first to make the inventions

covered by the issued patents or pending patent applications that we own or have exclusively licensed; • we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, results of operations and prospects. Risks Related to Government Regulation Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny. If one or more of our product candidates is approved, each will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP or similar regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP or similar regulations and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label and truthful and non- misleading. As such, we may not promote our products " off- label " for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post- marketing study or failure to complete such a study could result in the withdrawal of marketing approval. If a regulatory agency discovers 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 disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things: • issue warning **or untitled** letters; • impose civil or criminal penalties; • suspend, vary or revoke regulatory approval; • suspend any of our clinical studies; • refuse to approve pending applications or supplements to approved applications submitted by us; • impose restrictions on our operations, including closing our contract manufacturers' facilities; or • seize or detain products, or require or request a product recall. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the CARES Act made a number of changes to the Federal Food, Drug and Cosmetic Act aimed at preventing drug shortages. ~~Similarly~~ **The FDA issued Draft Guidance for Industry , Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD & C Act in April 2023, which recommends that applicants and manufacturers provide additional details and follow additional procedures to ensure** the FDA has ~~issued a number of guidance documents describing~~ the ~~agency' s expectations~~ **specific information it needs to help prevent for ~~-~~ or mitigate shortages and explains** how **the** ~~drug manufacturers should comply with various~~ FDA **communicates information about products in shortage** ~~requirements during the pandemic, including with respect~~ to **the public** ~~conducting clinical trials, distributing drug samples, and reporting post- marketing adverse events~~ . Moreover ~~, as a result of the COVID- 19 pandemic~~ , there has been increasing political and regulatory scrutiny of foreign- sourced drugs and foreign drug supply chains, resulting in proposed and enacted legislative and executive actions, including Executive Orders, to incentivize or compel drug manufacturing operations to relocate to the United States. It is not clear how these changes and proposals could impact our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. We may seek orphan drug designation for certain future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced. We may pursue orphan drug designation for certain of our future product candidates. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the European Commission, on the basis of a scientific opinion by the EMA' s Committee for Orphan Medicinal Products (COMP), grants orphan drug designation to promote the development

of products that are intended for the diagnosis, prevention, or treatment of a life- threatening or chronically debilitating condition affecting not more than five in 10, 000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life- threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product. In any event, orphan designation is granted only if there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. It is no longer necessary to obtain orphan designation in Great Britain before an application for marketing authorization is made, and the criteria will be assessed by the MHRA, at the time of assessment of the application for marketing authorization. The criteria in Great Britain are similar to those in the EU but have been tailored for the Great Britain market. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for certain clinical trial costs, and application fee waivers. In addition, if an orphan- designated product receives the first FDA approval for the indication for which it has orphan designation (meaning that FDA has not previously approved a drug considered the same drug for same orphan condition), the product is entitled to orphan drug exclusivity. If there is a previously approved same drug for the same orphan condition, to obtain orphan exclusivity, the sponsor of the subsequent drug must demonstrate clinical superiority over the previously approved same drug. If granted, orphan exclusivity means the FDA may not approve any other application to market the same drug for the same disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity to meet the needs of the orphan patient population. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval, subject to the positive outcome of the reassessment of the continued compliance with the orphan designation criteria at the time of approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met at the end of the fifth year since grant of the approval, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Moreover, upcoming legislative reforms in the European Union may result in a reduction of market exclusivity periods for orphan medicinal products and / or imposition of additional requirements for grant of such exclusivity. In Great Britain, if the criteria for orphan designation are met at the time of assessment of the marketing authorization, the applicant is entitled to a fee reduction and ten years of market exclusivity. The terms of market exclusivity, and possibility for the period to be reduced, are similar to those in the EU. ~~The~~ **On April 26, 2023, the** European Commission ~~is expected to publish~~ **published** new proposed legislation ~~in March 2023~~ which, if adopted by the European Parliament and the Council of Ministers, will introduce significant number of changes to the market exclusivities granted to orphan medicinal products and the related procedures and requirements in the EU **. The legislative procedure is not expected to conclude before 2024 / 2025 at the earliest** . Even if we obtain orphan drug designation for a product candidate, we may not be the first to obtain marketing approval for the product candidate for any particular orphan indication due to the uncertainties associated with developing novel biologic products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or foreign regulatory authorities can subsequently approve the same drug with the same active moiety for the same condition if the FDA or foreign regulatory authorities concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process. Moreover, a September 2021 Eleventh Circuit decision in Catalyst Pharmaceuticals, Inc. vs. Becerra regarding interpretation of the Orphan Drug Act exclusivity provisions as applied to drugs approved for orphan indications narrower than the drug' s orphan designation could significantly broaden the scope of orphan drug exclusivity for such products. In January 2023, FDA, however, issued a Federal Register notice clarifying its approach to orphan drug exclusivity following the Catalyst decision that suggests this may not be the agency' s intended direction going forward. Consistent with the court' s decision, FDA set aside its approval of the drug at issue in the case. But otherwise, the notification announced that at this time, while complying with the court' s order in Catalyst, FDA intends to continue to apply its regulations tying the scope of orphan- drug exclusivity to the uses or indications for which a drug is approved to matters beyond the scope of that order. Specifically, FDA intends to continue to apply its longstanding regulations tying the scope of orphan drug exclusivity to the uses or indications for which the orphan drug was approved. Legislation also has been introduced that may reverse the Catalyst decision. A fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval. We have received fast track designation for GRANITE for the treatment of colorectal cancer, and we may seek such designation for some or all of our other product candidates. If a drug or biologic, in our case, is intended for the treatment of a serious or life- threatening disease or condition and the biologic demonstrates the potential to address unmet medical needs for this disease or condition, the biologic sponsor may apply for FDA fast track designation. The sponsor of a fast- track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development; and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot guarantee that the FDA would grant it. Even if we do receive fast track designation, we may not

experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Some of our product candidates may require pediatric development, which may delay our regulatory approvals and ultimately our commercial licensure. The RACE for Children Act enacted in the U. S. in August 2017 and the European Pediatric Regulation implemented in 2007 as well as similar legislation in the UK may require us to develop our products in pediatric cancer patients. Pediatric cancers are rare, mutational burden is usually low in pediatric tumors and our approach may not be suited for children with cancer, or it may be difficult and slow to accrue children with cancers in our clinical trials. We may incur delays in meeting potential regulatory obligations or require additional investments to fulfill our regulatory commitments, and ultimately may be found incompliant if we cannot deliver pediatric data within the agreed timelines. This could lead to delays in regulatory approval and ultimately commercial licensure of our GRANITE or SLATE products **. On April 26, 2023, the European Commission published new proposed legislation which, if adopted by the European Parliament and the Council of Ministers, will introduce additional requirements in the EU. The legislative procedure is not expected to conclude before 2024 / 2025 at the earliest** . Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set. In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following: • an annual, non- deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs; • a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; • expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133 % of the federal poverty level, thereby potentially increasing a manufacturer' s Medicaid rebate liability; • a licensure framework for follow on biologic products; • a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and • establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Furthermore, the expansion of the 340B Drug Discount Program through the ACA has increased the number of purchasers who are eligible for significant discounts on branded drugs. Several drug manufacturers have commenced litigation, which remains ongoing, challenging the legality of contract pharmacy arrangements under the 340B Drug Discount Program, which may affect the way in which manufacturers are required to extend the 340B Drug Discount Program prices to covered entities, including through contract pharmacies. There are also ongoing challenges regarding the implementation of the 340B Drug Discount Program Administrative Dispute Resolution Process, which is in part intended to resolve claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers. In November 2022, the Health Resources and Services Administration issued a proposed rule to establish and implement an administrative dispute resolution process for certain disputes arising ~~hunder~~ **under** the 340B drug pricing program. The public comment period closed on January 30, 2023. The nature of the Administrative Dispute Resolution Process, once finalized, may have a material adverse impact on our revenue should we participate in the 340B Drug Discount Program after receiving approval for our product candidates. **It also is possible that Congress could consider legislation that amends or reforms the 340B Drug Discount Program.** Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed a ~~recent~~ judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court' s decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace during the COVID- 19 pandemic. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA **. There is also ongoing litigation challenging the legality of the ACA' s requirement that plans cover certain preventive services without cost- sharing** . In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which went into effect April 1, 2013 and due to subsequent legislative amendments, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, absent further congressional action. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations. Additionally, Congress has considered a number of bills relating to drug pricing and recently enacted the Inflation Reduction Act of 2022 (IRA), which was signed into law by President Biden and contains a number of provisions regarding drug pricing. The IRA adopted drug pricing reforms that will allow the federal government to negotiate prices for some high- cost drugs covered under Medicare Parts B and D, introduce inflationary rebates on certain

Medicare Part B and Medicare Part D drugs , and redesign the structure of the Part D benefit. ~~It remains unclear~~ **Starting in June 2023, several manufacturers and trade associations commenced litigation challenging the legality of the IRA' s Negotiation Program. We cannot predict the outcome of these cases,** how numerous aspects of this law will be implemented , and how it will affect our business **. It** ~~, and it~~ is **also** possible that Congress will consider other legislation that would affect drug pricing issues going forward. ~~Although the Build Back Better Act stalled in Congress, there are other drug pricing reforms still under consideration in Congress, including elements of the Build Back Better Act aimed at allowing Medicare to negotiate the price of prescription drugs in the United States.~~ Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries, hearings and proposed and enacted federal legislation and rules, as well as Executive Orders, designed to, among other things, reduce or limit the prices of drugs and make them more affordable for patients, such as by tying the prices that Medicare reimburses for physician-administered drugs to the prices of drugs in other countries, bring more transparency to drug pricing rationale and methodologies (including, for example, by requiring drug manufacturers to disclose planned drug price increases and the rationales for such increases), implement data collection and reporting under Section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021, which requires, among other things, health plans and issuers to disclose rebates, fees, and other remuneration provided by drug manufacturers related to certain pharmaceutical products, revise rules associated with the calculation of Medicaid Average Manufacturer Price and Best Price, including the removal of the current statutory 100 % of Average Manufacturer Price per- unit cap on Medicaid rebate liability for single source and innovator multiple source drugs effective as of January 1, 2024 under the American Rescue Plan Act of 2021, which may significantly affect the amount of rebates paid on prescription drugs under Medicaid and the prices that are required to be charged to covered entities under the 340B Drug Discount Program, and facilitate the importation of certain lower- cost drugs from other countries. In July 2021, President Biden issued an Executive Order directing various executive branch agencies to take actions to lower drug prices and promote generic competition, including directing FDA to support and work with states and Indian Tribes to develop importation plans to import prescription drugs from Canada. The Executive Order **also** required the Secretary of Health and Human Services to develop a comprehensive plan for addressing drug prices. The plan was released on September 9, 2021, and it includes support for legislative and administrative actions that would improve affordability, access and competition, and foster scientific innovation **. In January 2024, FDA authorized Florida' s Section 804 importation program to facilitate importation of certain prescription drugs from Canada** . Following passage of the IRA, in October 2022, President Biden issued an Executive Order directing the Center for Medicare and Medicaid Innovation to consider new models to lower drug costs and promote access to Medicare and Medicaid beneficiaries. The Executive Order directs HHS to issue a report on potential models to the White House within 90 days, and HHS delivered a report to President Biden on February 14, 2023 that outlines three models, including one that would develop payment methods for drugs approved under accelerated approval, in consultation with the Food and Drug Administration, to encourage timely confirmatory trial completion and improve access to post market safety and efficacy data. It is possible that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. **In May 2023, CMS issued a Medicaid Drug Rebate Program proposed rule, which if finalized, could increase manufacturer responsibilities and rebate liability under the program.** Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing. In the European Union and UK, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever- increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Moreover, upcoming legislative and policy changes in the European Union may further impact the price and reimbursement status of our products in the future. Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare

professionals, consultants, third- party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include: • the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebates), 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, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U. S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the U. S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; • HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U. S. federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation; • the Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; • the U. S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product; • the U. S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (as defined by statute), certain non- physician practitioners such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; • analogous U. S. state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; • the U. S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U. S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and • similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers. Ensuring that our internal operations and future 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, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government- funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non- compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time- consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Risks Related to Our Common Stock The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed **elsewhere** in this " Risk Factors " section of this report and others such as: • results from, and any delays in, our clinical trials, in particular for GRANITE ~~and~~ **,** SLATE **, CORAL** or any other current or future clinical development programs, including public misperception of the results of our trials; • announcements by academic or other third parties challenging the fundamental premises underlying our approach to treating cancer and infectious disease and / or biopharmaceutical product development; • announcements of regulatory approval or disapproval of our current or any future product candidates; • failure or discontinuation

of any of our research and development programs; • manufacturing setbacks or delays of or issues with the supply of the materials for our personalized immunotherapy candidate; • announcements relating to future licensing, collaboration or development agreements, including the early termination or failure of an existing strategic collaboration; • delays in the commercialization of our current or any future product candidates; • public misperception regarding the use of our therapies; • acquisitions and sales of new products, technologies or businesses; • quarterly variations in our results of operations or those of our current or future competitors; • changes in earnings estimates or recommendations by securities analysts; • announcements by us or our competitors of new products, significant contracts, commercial relationships, acquisitions or capital commitments; • developments with respect to intellectual property rights; • our commencement of, or involvement in, litigation; • changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance; • any major changes in our board of directors or management; • new legislation, particularly in the United States, relating to the sale or pricing of pharmaceuticals; • FDA or other U. S. or foreign regulatory actions affecting us or our industry; • product liability claims or other litigation or public concern about the safety of our product candidates; • market conditions in the biopharmaceutical and biotechnology sectors ~~, particularly as a result of the volatility in the market caused by the COVID- 19 pandemic~~ ; and • general economic **, industry and market** conditions in the United States and abroad **, including recent instability in the banking sector, inflation and market volatility, rising interest rates, the federal debt ceiling and budget the potential for government shutdowns, and the ongoing labor shortage** . In addition, the stock ~~markets~~ **market** in general, and the markets for biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility **, including as a result of recent instability in the banking sector, increases in inflation and market volatility, rising interest rates, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, disruptions to global supply chains, cybersecurity events and regional conflicts around the world,** that ~~may~~ have **often** been unrelated to the operating performance of any particular issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit, and the attention of our management would be diverted from the operation of our business. The future issuance of equity or of debt securities that are convertible into equity will dilute our share capital. We **expect that significant** ~~may choose to raise~~ additional capital **may be needed** in the future **to continue our planned** ~~, depending on market conditions, strategic considerations and operational~~ **operations** ~~requirements~~ **. To raise capital, we may sell common stock, convertible securities or other equity or debt securities in one or more transactions at prices and in a manner we determine from time to time** . For example, we have issued and may continue to issue shares in our " at the market offering " program or other registered offerings ~~under our 2022 Shelf Registration Statement~~ , and we have issued shares in three private placement of public issuer' s equity transactions. To the extent that additional capital is raised through the issuance of shares of common stock or other securities convertible into shares of common stock, our stockholders will be diluted. In addition, future issuances of our common stock or other equity securities (or securities convertible into our common stock or other equity securities), or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or other securities. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, ~~2022~~ **2023** , we have a total of ~~86~~ **97** , ~~894~~ **585** , ~~901~~ **415** shares of common stock outstanding, as well as approximately ~~26~~ **20** . ~~8~~ **5** million shares underlying pre- funded warrants and approximately ~~7~~ **10** . ~~7~~ **6** million shares of common stock that are subject to outstanding options, restricted stock units or other equity awards. ~~If~~ **We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, if** these ~~additional~~ shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial **net operating** losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. **Under current law, federal net operating** ~~To the extent that we continue to generate taxable~~ losses **generated in tax years beginning after December 31** , ~~unused~~ **2017 will not expire and may be carried forward indefinitely but the deductibility of such federal net operating** losses ~~will carry forward~~ **for any year is limited** to ~~offset a portion~~ **no more than 80 %** of ~~future~~ **the excess, if any, of current year** taxable income **(without regard to certain deductions)** ~~, if any, until such unused losses expire, if ever~~ . **In addition,** ~~Under~~ **under** Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (IRC), if **we** ~~a corporation undergoes~~ -- **undergo** an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period, **our** ~~the corporation' s~~ ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes (such as research and development tax credits) to offset its post- change income or taxes may be limited. ~~Any~~ **It is possible that we may have undergone one or more " ownership changes " in the past. In addition, any** equity financing transactions, private placements and other transactions that occur **in** ~~within a three~~ -- **the** ~~- year testing period~~ **future, some of which are outside of our control,** may trigger additional ownership changes, which could further limit our use of such **net operating losses or other pre- change** tax attributes. ~~Any such limitations~~ **Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition** , ~~whether as~~ **at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As** a result **, even if we attain profitability, we may be unable to use all or a material portion** of ~~prior or~~ **our net operating losses and other tax attributes, which could adversely affect our results of operations and** future **cash flows** ~~offerings of our common stock or sales of common stock by existing stockholders, could have an adverse effect on our results of operations~~

~~in our future years~~ . Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management. Our amended and restated certificate of incorporation **, as amended,** and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following: • a classified board of directors with three- year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors; • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; • the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror; • the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval; • the required approval of at least 66 2 / 3 % of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation **, as amended,** regarding the election and removal of directors; • a prohibition on stockholder action by written consent, which force stockholder action to be taken at an annual or special meeting of our stockholders; • the requirement that a special meeting of stockholders may be called only by our chief executive officer or president or by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and • advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror' s own slate of directors or otherwise attempting to obtain control of us. We are also subject to the anti- takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, 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 exceptions, the board of directors has approved the transaction. Our amended and restated certificate of incorporation **, as amended,** and our amended and restated bylaws provide for an exclusive forum in the Court of Chancery of the State of Delaware and in the U. S. federal district courts for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation **, as amended,** and our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation **, as amended,** or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, our amended and restated certificate of incorporation **, as amended,** provides that the U. S. federal district courts are the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. The choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. ~~Risks related~~ **We do not currently intend** to **pay dividends on our common stock, and, consequently,** ~~our~~ **your ability** ~~Loan Agreement Our failure~~ to **achieve a return on** ~~comply with the covenants or payment obligations under our~~ **your investment will depend on appreciation** ~~existing term loan facility could result~~ in ~~an event~~ **the price** of ~~default, which may result in increased interest charges, acceleration of our repayment obligations or~~ **our** ~~other actions by the lenders,~~ **common stock. We have never declared or paid cash dividends on our capital stock. We do not currently intend to pay** any **cash dividends on** ~~of which could negatively impact our business, financial condition and results of operations. On July 19, 2022, we entered into a Loan and Security Agreement (the " Loan Agreement ") with Hercules Capital, Inc., Silicon Valley Bank, and certain financial institutions or~~ **our common stock for** ~~other~~ -- **the foreseeable future** ~~entities from time- to- time party thereto (the " Lenders ") pursuant to which the Lenders made available to us a secured term loan facility in an aggregate principal amount of up to $ 80 million (the " Term Loan ")~~ . We **currently intend to invest** ~~immediately drew $ 20. 0 million under this facility upon entry into the Loan Agreement. In connection with the Loan Agreement, we granted the Lenders a security interest in substantially all of~~ our **future earnings** ~~personal property and other assets~~ , **if any** ~~other than our intellectual property. The Loan Agreement contains customary affirmative and restrictive covenants and representations and warranties~~ , **to fund our growth. Therefore** ~~including a covenant against the occurrence of a change in control (as defined by the Loan Agreement)~~ , ~~financial reporting obligations, and certain limitations~~ **you are not likely to receive any dividends** on ~~indebtedness~~ **your common stock for the foreseeable future. Since we do not intend to pay dividends** , ~~liens (including~~ **your ability to receive** a **return** ~~negative pledge~~ on **your** ~~intellectual property and other assets), investments~~ - **investment will depend** , distributions (including dividends),..... other actions may have a negative impact on ~~our business, financial condition and results of operations. Our existing and~~ any future ~~indebtedness may limit~~ **appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate** ~~our~~ - **or even maintain** ~~cash flow available to invest in the ongoing needs of our business. Our outstanding debt combined with our other~~ -- **the price at which our holders** ~~financial obligations and contractual commitments could~~ have **purchased it** significant adverse consequences, including: •..... interests in the collateral securing such indebtedness . General Risk Factors If securities or

industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business **. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports** . If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. We incur substantial costs as a result of operating as a public company, and our management devotes substantial time to governance and compliance matters. **Any failure** ~~We may fail~~ to comply with the rules that apply to public companies, including Section 404 of the Sarbanes- Oxley Act of 2002, ~~which~~ could result in sanctions or other penalties that would harm our business. We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq Global Select Market and the rules of the SEC require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct, among other requirements. Our management and other personnel devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms or at all. As a public company, we are subject to Section 404 of the Sarbanes- Oxley Act of 2002 (Section 404) and the related rules of the SEC, which generally require **that we maintain effective internal controls for financial reporting and disclosure controls and procedures and that** our management and independent registered public accounting firm ~~to~~ report on **, among other things,** the effectiveness of our internal control over financial reporting. **This assessment needs to include disclosure of** ~~However, for so long as we remain an~~ **any** ~~emerging growth company as defined~~ **material weaknesses identified by our management** in **our internal control over financial** ~~the JOBS Act, we intend to take advantage of certain exemptions from various~~ reporting ~~requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404~~ . ~~Once~~ **As of December 31, 2023,** we are no longer an emerging growth company ~~or~~ **and** , **therefore** ~~if prior to such date~~ , ~~we opt~~ **are subject** to **certain additional public company reporting obligations. However, although we are** no longer ~~take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain~~ an emerging growth company ~~until December 31~~ , ~~2023. In order~~ **we are still a smaller reporting company and a non- accelerated filer, and as such, we are not required** to **comply with the auditor attestation requirements of Section 404. To** provide the reports required by these rules we must conduct reviews and testing of our internal controls. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. **To** ~~In order to~~ report our results of operations and financial statements on an accurate and timely basis, we will depend on third party vendors to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm our business. Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to us. Our amended and restated certificate of incorporation **, as amended,** and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that: • We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person' s conduct was unlawful. • We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law. • We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification. • We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification. • The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements

with our directors, officers, employees and agents and to obtain insurance to indemnify such persons. • We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents. ~~We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock. We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.~~