Risk Factors Comparison 2024-03-25 to 2023-03-30 Form: 10-K

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Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this annual report **on Form 10- K** , including our financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. Risks Related to Our Business We are a clinical stage biopharmaceutical company with ~~a limited operating history and~~ no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability, which could result in a decline in the market value of our common stock. We are a clinical stage biopharmaceutical company ~~with a limited operating history on which to base your investment decision~~ . Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we ~~have enrolled a limited number of patients in our initial clinical trials,~~ have no products approved for commercial sale, have not generated any revenue from commercial product sales and, as of December 31, ~~2022~~ **2023** , had an accumulated deficit of $ ~~452~~ **559** . ~~6~~ **4** million. For the years ended December 31, ~~2022~~ **2023** ~~,~~ and December 31, ~~2021~~ **2022** , our net loss was $ **106. 8 million and $** 119. 2 ~~million and $ 105. 5~~ million, respectively. 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. In addition, our expenses could increase beyond expectations if we are required by the FDA, or foreign regulatory agencies, to perform studies or clinical trials in addition to those studies and clinical trials that we currently anticipate conducting for our product candidates, or if there are any delays in our or our partners completing clinical trials or the development of any of our product candidates. Our technologies and product candidates are in ~~early~~ **varying** stages of development, and we are subject to the risks of failure inherent in the development of product candidates based on novel technologies. In addition, we ~~have limited experience as a clinical stage company and~~ have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. Furthermore, we do not expect to generate any revenue from commercial product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials and the regulatory approval process for **our product candidates and manufacturing clinical and early commercial supply of** our product candidates. We expect our net losses to increase substantially as we progress further into clinical development of our lead programs and create additional infrastructure to support operations as a public company. However, the amount of our future losses is uncertain. We may never generate revenues from the commercial sale of our or our collaborators' products. Our ability to achieve profitability, if ever, will depend on, among other things, our, or our existing or future collaborators', successful development of product candidates, evaluating the related commercial opportunities, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third- party alternatives for any approved product, and raising sufficient funds to finance business activities. If we, or our existing or future collaborators, are unable to develop our technologies and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We will need substantial additional funds to advance development of our product candidates **and** ~~. This additional financing may not be available on acceptable terms, or at all. Failure~~ **failure** to obtain **sufficient funding** ~~this necessary capital when needed~~ may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations. **We** ~~Continued unfavorable conditions in the capital markets~~ may ~~pose~~ **have** ~~difficulties~~ **difficulty** ~~to us in~~ accessing additional capital on reasonable, or even any, terms to continue our product and platform development or other operations ~~. In addition,~~ **and may have to** ~~market~~ -- **make difficult prioritization decisions regarding development** ~~volatility, high levels of inflation~~ and ~~interest rate fluctuations may increase our cost of capital or otherwise restrict our access to~~ potential ~~sources~~ **partnering** of ~~future liquidity~~ **our clinical and preclinical product candidates** . The development of biopharmaceutical product candidates is capital- intensive. ~~If~~ **As** our product candidates ~~enter and~~ advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial funds to develop our technology and product candidates and will require significant funds to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates, to manufacture extract and products, if any, which may be approved for commercial sale, to establish marketing and sales capabilities to commercialize our product candidates, and to provide support to our collaborators in the development of their products. In addition, we expect to continue to incur additional costs associated with operating as a public company. Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our ~~two proprietary~~ clinical- stage product candidates ~~luvelta and STRO- 001,~~ and the development

of our technology platform, including our in- house manufacturing capabilities. Clinical trials for our product candidates have required substantial funds to date and will continue to require substantial funds to complete. As of December 31, ~~2022~~ **2023**, we had $ ~~302~~ **333**. ~~3~~ **7** million in cash, cash equivalents and marketable securities. We expect to incur substantial expenditures in the foreseeable future as we seek to advance **multiple** ~~luvelta, STRO- 001 and STRO- 003 and any future~~ product candidates through clinical development, manufacturing, the regulatory approval process and, if approved, commercial launch activities, as well as in connection with the continued development of our technology platform and manufacturing capabilities. Based on our current operating plan, we believe that our available cash, cash equivalents and marketable securities will be sufficient to fund our operations through at least the next 12 months. However, our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect, and we may need to seek additional funds sooner than planned. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. ~~The~~ **For example, the** timing and amount of our operating expenditures will depend largely on: • the timing ~~and~~ **,** progress **and results** of preclinical and **worldwide** clinical development activities; • the costs associated with the development of our internal manufacturing and research and development facilities and processes; • the number and scope of preclinical and clinical programs we decide to pursue; • the progress of the development efforts of parties with whom we have entered or may in the future enter into collaborations and research and development agreements; • the timing and amount of milestone and other payments we may receive under our collaboration **and / or research and development** agreements; • our ability to **establish and** maintain ~~our current licenses and research and development programs and to establish new collaboration~~ **collaborations , strategic partnerships or marketing, distribution, licensing or other strategic** arrangements **with third parties on favorable terms, if at all; • our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third- party payors and adequate market share and revenue for any approved product candidates** ; • the costs involved in prosecuting, defending and enforcing patent and other intellectual property claims; • the costs of manufacturing our product candidates and those of our collaborators using our proprietary XpressCF ® and XpressCF ® platforms; • the cost and timing of regulatory approvals; • the cost of commercialization activities if our product candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs; • our efforts to enhance operational systems and hire and retain **key** personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company; and • general economic, industry and market conditions, including market volatility, high levels of inflation ~~and~~ **, changes in** interest ~~rate~~ **rates** ~~fluctuations~~ **, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto** . If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. We cannot provide assurance that anticipated collaborator payments will, in fact, be received. We do not expect to realize revenue from sales of commercial products or royalties from licensed products in the foreseeable future, if at all, and, in no event, before our product candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through payments received under our collaboration and other associated agreements, the sale of equity securities ~~and~~ **,** debt financing **and a royalty monetization agreement** . We will be required to seek additional funding in the future and currently intend to do so through additional collaborations and / or licensing agreements, public or private equity offerings or debt financings, credit or loan facilities, **royalty monetization** 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, including the factors impacting potential interest rates for any debt financings~~ . Additional funds may not be available to us on acceptable terms or at all ~~. In addition, current macroeconomic conditions have caused turmoil in the banking sector. For example, on March 10, 2023, SVB one of our banking partners and lenders, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Under the terms of our Loan and Security Agreement, we were required to keep substantially all of our cash and investments with SVB, the substantial majority of which was held in a custodial account with another institution, for which SVB Asset Management was the advisor. While we were afforded full access to our cash and investments with SVB on March 13, 2023, and have since amended our Loan and Security Agreement to provide us with greater cash management flexibility, we may be impacted by other disruptions to the U. S. banking system, including potential delays in our ability to transfer funds whether held with SVB or otherwise and in the short- term potential delays in making payments to vendors while new banking relationships are established. Subject to limited exceptions, our Loan and Security Agreement with Oxford and SVB prohibits us from incurring indebtedness without the prior written consent of Oxford and SVB~~ . 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. 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, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. **Any** ~~Our current debt financing involves, and~~ future debt financings, if available, are likely to involve, restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our corporate assets. Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have

a material and adverse effect on our business, financial condition, results of operations and prospects. Our product candidates are in ~~early~~ **varying development** stages ~~of development~~ and may fail in development or be impacted by competitive products or suffer delays that materially and adversely affect their commercial viability. If we or our collaborators are unable to complete development of or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed. We have no products on the market and all of our product candidates for cancer therapy are in **clinical** ~~early stages of~~ development. **Our** ~~In particular, our~~ most advanced product candidate, luvelta, is **being evaluated** in **REFRαME- O1, a** ~~the dose expansion phase of its~~ Phase **2 / 3 pivotal** ~~1 clinical trials. Also, enrollment began in the second half of 2019 for patients in the Phase 1 clinical~~ trial for ~~CC- 99712~~ **treatment of women with platinum resistant ovarian cancer** , **as well as** ~~a BCMA ADC candidate resulting from our BMS collaboration. Merck initiated patient dosing~~ in **additional** ~~a Phase 1~~ clinical ~~trial~~ **studies underway, including** for **treatment** ~~MK- 1484 in July 2022, a product candidate resulting from our cytokine- derivative collaboration. In the first quarter~~ of **women with endometrial cancer** ~~2022, Vaxcyte announced that it had initiated a Phase 1 / 2 clinical proof- of- concept study of its lead product candidate, VAX- 24, its 24- valent pneumococcal conjugate vaccine candidate, under investigation for the prevention of invasive pneumococcal disease in adults,~~ and **children with pediatric AML** ~~announced initial data in October 2022~~ . Additionally, we have programs that are **being evaluated by partners in clinical trials and by us** in earlier stages of discovery and preclinical development and may never advance to clinical- stage development. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including: • negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program; • product- related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologics similar to our product candidates; • difficulty achieving successful continued development **, or transfer to third- parties,** of our internal manufacturing processes, including process development and scale- up activities to supply products for preclinical studies, clinical trials and commercial sale ~~; • our inability to successfully transfer our manufacturing expertise and techniques to third- party contract manufacturers; • inability of us or any third- party contract manufacturer to scale- up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials and commercial sales, and to manufacture such products in conformity with regulatory requirements using our proprietary XpressCF ® and XpressCF ® platforms~~ ; • delays in submitting INDs or comparable foreign applications or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced; • conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials; • delays in enrolling patients ~~in our~~ **or** ~~clinical trials; •~~ high drop- out rates ~~of~~ **in** our clinical ~~trial~~ **trials** ~~patients~~ ; • inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials; • inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials; • occurrence of epidemics, pandemics or contagious diseases ~~, such as the novel strain of coronavirus,~~ and potential effects on our business, clinical trial sites, **highly complex** supply chain and manufacturing facilities; • greater than anticipated costs of our clinical ~~trials~~ **programs** ; • harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials **, which can be unpredictable even in light of earlier non- clinical and clinical data** ; • failure to demonstrate in our clinical trials a sufficient response rate or duration of response; • failure to demonstrate a benefit- risk profile acceptable to the FDA or other regulatory agencies; • unfavorable FDA or other regulatory agency inspection and review of one or more of our clinical trial sites or manufacturing facilities; • failure of our third- party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all; • delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; and • varying interpretations of our data by the FDA and similar foreign regulatory agencies. We or our collaborators' inability to complete development of or commercialize our product candidates or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects. Our business is dependent on the success of our product candidates ~~based on~~ **, including luvelta, which is generated from** our proprietary XpressCF ® and XpressCF ® platforms ~~and, in particular, our proprietary product candidates, luvelta, STRO- 001 and STRO- 003~~ . Existing and future preclinical studies and clinical trials of our product candidates may not be successful. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed. We have invested a significant portion of our efforts and financial resources in the development of our proprietary XpressCF ® and XpressCF ® platforms and our proprietary product candidates, luvelta, STRO- ~~001~~ **003** and STRO- ~~003~~ **004** . Our ability to generate commercial product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of **our product candidates** ~~luvelta, STRO- 001 and STRO- 003~~ . We have not previously submitted a new drug application, or NDA, or a biologics license application, or BLA, to the FDA, or similar regulatory approval filings 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. In addition, although we believe that our REFRαME- O1 Phase 2 / 3 pivotal trial of luvelta for the treatment of women with platinum resistant ovarian cancer will provide a sufficient**

dataset to support submission of a BLA to the FDA or equivalent to regulatory agencies, we cannot assure you that the FDA will agree with our conclusions or require data prior to approval. Further, our 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 our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for 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 approvals generally is similar in other countries, in order to obtain separate regulatory approvals in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding 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 to comply with ongoing regulations in these jurisdictions. The success of luvelta, STRO- ~~001~~ **003** and STRO- ~~003~~ **004** and our other future product candidates will depend on many factors, including the following: • successful enrollment of patients in, and the completion of, our clinical trials; • receiving required regulatory approvals for the development and commercialization of our product candidates; • establishing our commercial manufacturing capabilities or making arrangements with third- party manufacturers; • establishing successful technology transfers and collaborations to develop our product candidates with licensees, including our licensees with rights to luvelta ~~and STRO- 001~~ in Greater China; • obtaining and maintaining patent, trademark and trade secret protection and non- patent exclusivity for our product candidates and their components; • enforcing and defending our intellectual property rights and claims and avoiding or defending against intellectual property rights and claims from third parties; • achieving desirable therapeutic properties for our product candidates' intended indications; • launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with third parties; • acceptance of our product candidates, if and when approved, by patients, the medical community and third- party payors; • effectively competing with other therapies **, including those that have not yet entered the market** ; ~~and~~ • maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory approval **; and • achieving commercially relevant success in the market post approval** . ~~If~~ **Many of these factors are out of our control and if** we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects ~~trials~~ .Patient enrollment,a significant factor in the timing of clinical trials,is affected by many factors including the size and nature of the patient population,the proximity of patients to clinical sites,the eligibility criteria for the trial,the design of the clinical trial,competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies,including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us.Furthermore,we expect to rely on our collaborators,CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and,while we expect to enter into agreements governing their committed activities,we have limited influence over their actual performance.We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy **profiles** . Additionally, we have in the past and may in the future create benchmark molecules for comparative purposes. For example, we have created a benchmark FolRα targeting antibody- drug conjugate, or ADC, using conventional technology that results in a heterogeneous ADC mixture. We have compared luvelta to this benchmark molecule in multiple preclinical models. We believe the results of these tests help us understand how the therapeutic index of luvelta compares to competitors' product candidates. However, we cannot be certain that any benchmark molecule that we create is the same as the molecule we are attempting to recreate, and the results of the tests comparing any such benchmark molecule to any other potential or current product candidate may be different than the actual results of a head- to- head test of any such other potential or current product candidate against a competitor molecule. Additional preclinical and clinical testing will be needed to evaluate the therapeutic index of our potential or current product candidates, and to understand their therapeutic potential relative to other product candidates in development. While we believe our ADCs may be superior to other investigative agents in development, without head- to- head comparative data, we will not be able to make claims of superiority to other products in our promotional materials, if our product candidates are approved. If we do not achieve our projected development goals in the time frames we anticipate and project, the commercialization of our products may be delayed and our stock price may decline. From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory, commercial and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control **, such as health epidemics and pandemics, global instability and geopolitical conflicts within regions where our clinical trials are conducted. For example, we intend to open a clinical trial site in Israel, which may face enrollment, operational or other difficulties due to conflicts within the region, including, for example, difficulties importing clinical study drug through Israeli customs, difficulties with patient enrollment, or difficulties with patients or medical personnel accessing appropriate medical facilities. In addition, we rely on third party vendors, contractors and consultants to provide services in connection with our clinical trials. If these third parties do not perform their services in a timely or workmanlike manner, our clinical studies may be delayed** . If we do not meet these milestones as publicly announced, or at all, the commercialization of our products ~~maybe~~ -- **may be** delayed or never achieved and, as a result, our stock price may

decline ~~. For example, even with the approval of vaccines for COVID- 19, the COVID- 19 pandemic may further delay enrollment in trials due to prioritization of hospital resources toward the pandemic, restrictions on travel, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results~~ . Our approach to the discovery and development of our therapeutic treatments is based on novel technologies, including unprecedented Immunostimulatory Antibody Drug Conjugate, or iADC, and dual Antibody Drug Conjugates, or ADC2 technology, that are unproven and may not result in marketable products. We are developing a pipeline of product candidates using our proprietary XpressCF ® and XpressCF ® platforms. We believe that product candidates identified with our product discovery platform may offer an improved therapeutic approach by taking advantage of precision design and rapid empirical optimization, thereby reducing the dose- limiting toxic effects associated with existing products. However, the scientific research that forms the basis of our efforts to develop product candidates based on our XpressCF ® and XpressCF ® platforms is ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our XpressCF ® and XpressCF ® platforms is both preliminary and limited. To date, ~~we have tested~~ our ~~first~~ clinical stage product candidates **have been** ~~, luvelta and STRO- 001, our partner BMS has~~ tested ~~CC- 99712, our partner Merck has tested MK- 1484, and our partner EMD Serono has tested M1231 in a limited number of clinical trial patients. In addition, Vaxcyte has tested its lead product candidate, VAX- 24, a 24- valent pneumococcal conjugate vaccine,~~ in a limited number of clinical trial patients. We may ultimately discover that our XpressCF ® and XpressCF ® platforms and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. XpressCF ® product candidates may also be unable to remain stable in the human body for the period of time required for the drug to reach the target tissue or they may trigger immune responses that inhibit the ability of the product candidate to reach the target tissue or that cause adverse side effects in humans. We currently have only limited data, and no conclusive evidence, to suggest that we can introduce these necessary properties into these product candidates derived from our XpressCF ® and XpressCF ® platforms. We may spend substantial funds attempting to introduce these properties and may never succeed in doing so. In addition, product candidates based on our XpressCF ® and XpressCF ® platforms may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Although our XpressCF ® and XpressCF ® platforms and certain product candidates have produced successful results in animal studies, they may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. Further, in our oncology clinical trials to date, we have used achievement of stable disease as evidence for disease control (stable disease, partial response or complete response) by our product candidates; however, the FDA does not view stable disease as an objective response for the purposes of FDA approval. **Results** ~~We presented updated data from the dose escalation portion~~ of **our clinical trials could reveal a high and unacceptable severity and prevalence of side effects** ~~our~~ **or** ~~STRO~~ **unexpected characteristics. Undesirable side effects could result in the delay, suspension or termination of clinical trials by us or regulatory authorities for a number of reasons. In our clinical trials to date, our product candidates have been generally well tolerated, and the most common treatment** ~~- 001 Phase 1 trial in December 2020. As of October 30, 2020, most treatment~~ emergent adverse events ~~were grade 1 or 2~~ , **or TEAEs, that resulted in a** ~~with the most common grade 1- 2~~ treatment ~~emergent~~ **delay or dose reduction was reversible neutropenia. We have also observed arthralgia as a TEAE. It is possible that, as we test our product candidates in larger, longer and more extensive clinical trials or as the use of our product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other** adverse events **that** ~~, or TEAEs, of nausea, fatigue, chills, anemia, headache, dyspnea, abdominal pain, vomiting, decreased appetite and pyrexia, and no ocular or neuropathy toxicity signals have been observed. Two grade 3 and no grade 4 treatment emergent adverse events~~ were observed **in earlier trials** , ~~one instance each of anemia and dyspnea. Subsequent to a~~ **as well as conditions that did not occur or went undetected in** ~~previously~~ -- **previous trials, will be reported by** ~~announced protocol amendment in 2019 requiring pre- treatment screening imaging for~~ patients ~~at risk~~ **. If such side effects become known later in development** ~~for~~ - **or** ~~thromboses~~ **upon approval** , **if any** ~~no thromboembolic events have been observed. We have completed phase 1 dose escalation in the STRO- 001 Phase 1 trial following identification of the maximum tolerated dose. We presented updated data from the dose escalation portion of our luvelta Phase 1 trial in May 2021. Based on data from the trial through April 23~~ , **such findings may harm** ~~2021, luvelta was generally well tolerated and was mostly associated with mild adverse events. Eighty- six percent (86 %) of observed adverse events were grade 1 or~~ **our business** ~~grade 2. The most common Grade 3 and 4 TEAEs were reversible neutropenia (64 %). Grade 3 arthralgia (13 %)~~ , **financial condition** ~~fatigue (10 %)~~ , ~~and neuropathy (8 %) were observed and managed with standard medical treatment, including dose reductions or delays. We released preliminary final~~ results of **operations** ~~the dose- expansion portion of our luvelta Phase 1 trial in January 2023. Safety signals from this portion of the trial were consistent with data from the dose- escalation cohort. Neutropenia was the leading TEAE that resulted in a treatment delay or dose reduction. Arthralgia was the second most common Grade 3 TEAE and second most common TEAE leading to dose reduction. There were also limited observed cases of febrile neutropenia, including one Grade 5 event at the 5. 2 mg / kg starting dose level and one Grade 3 event at the 4. 3 mg / kg starting dose level. The trial protocol was subsequently updated to require dose reduction for Grade 4 neutropenia. We also initiated an~~ **and prospects significantly** ~~exploratory cohort C to assess the safety of treatment with luvelta at 5. 2 mg / kg in combination with prophylactic pegfilgrastim and presented preliminary data from ten patients from this cohort in January 2023. Early results from these initial 10 patients in cohort C, when compared to patients who were not given prophylactic pegfilgrastim in the dose- expansion cohort at the 5. 2 mg / kg dose (n = 21) demonstrated substantial reductions in Grade 3 neutropenia and instances of dose delays~~ . If product candidates based on our XpressCF ® and XpressCF ® platforms are unable to demonstrate sufficient safety and efficacy data to obtain marketing approval, we may never succeed in developing a marketable product, we may not become profitable and the value of our common stock will decline. The regulatory approval process for novel product candidates such as ours can

be more expensive and take longer than for other, better known or extensively studied product candidates. We are not aware of any company currently developing a therapeutic using our approach to ADC, iADC or ADC2 development and no regulatory authority has granted approval for such a therapeutic. We believe the FDA has limited experience with therapeutics in oncology or other disease areas developed in cell- free- based synthesis systems, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. For example, our XpressCF ® ADC product candidates contain cleavable or non- cleavable linker- warhead combinations or novel warheads that may result in unforeseen events when administered in a human. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications 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 or an existing or future collaborator 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 the products resulting from our XpressCF ® platform prove to be ineffective, unsafe or commercially unviable, our entire platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects. Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and preliminary results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. While certain relevant members of our company have significant clinical experience, we in general have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, **current** or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial patients. In addition, results from compassionate use of our product candidates, such as luvelta to treat pediatric CFB / GLIS AML, ~~my~~ **may** not be confirmed in Company- sponsored trials and / or may negatively impact the prospects for marketing approval for our product candidates. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted. Interim, top- line, or preliminary data from our clinical trials that we announce may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we have publicly disclosed, and in the future will disclose, preliminary or top- line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Therefore, final results from the studies may differ from the top- line results initially reported, and the final results may indicate different conclusions once additional data have been evaluated. As such, top- line data should be viewed with caution until the final data are available. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive data, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the final results differ from the interim, top- line, or preliminary data, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and to commercialize, our product candidates may be harmed, which may negatively affect our business, financial condition, results of operations, and prospects. Moreover, from time to time, we have publicly disclosed, and in the future may disclose, interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the outcomes may materially change as patient enrollment continues and more data become available. Adverse differences between top- line, preliminary, or interim data, on the one hand, and final data, on the other, could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses, or may interpret or weigh the importance of data differently, which could negatively affect the approvability or commercialization of the particular product candidate. The market may not be receptive to our product candidates based on a novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates. Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost, competition in the therapeutic area (s) we have received or may receive approval for, and whether it will otherwise be accepted in the market. Historically, there have been concerns regarding the safety and efficacy of ADCs, and an ADC drug was voluntarily withdrawn from the market for an extended period of time. These historical concerns may negatively impact the perception market participants have on ADCs, including our product candidates. Additionally, the product candidates that we are developing are based on our proprietary XpressCF ® and XpressCF ® platforms, which are new technologies.

Market participants with significant influence over acceptance of new treatments, such as physicians and third- party payors, may not adopt an ADC product, or a product or treatment based on our novel cell- free production technologies, and we may not be able to convince the medical community and third- party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on **the following** , among other factors: • the timing of our receipt of any marketing and commercialization approvals; • the terms of any approvals and the countries in which approvals are obtained; • the safety and efficacy of our product candidates; • the prevalence and severity of any adverse side effects associated with our product candidates; • limitations or warnings contained in any labeling approved by the FDA or other regulatory authority; • relative convenience and ease of administration of our product candidates; • the willingness of patients to accept any new methods of administration; • the success of our physician education programs; • the availability of coverage and adequate reimbursement from government and third- party payors; • the pricing of our products, particularly as compared to alternative treatments; and • the availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments. Because our product candidates are based on new technology, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, our estimates regarding potential market size for any indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects. iADC and ADC2 are novel technologies, which makes it difficult to predict the time, risks and cost of development and of subsequently obtaining regulatory approval of these potential product candidates. Certain of our preclinical product candidates are based on our proprietary iADC and ADC2 technology. Some of our future success depends on the successful development of this technology and products based on it. To our knowledge, no regulatory authority has granted approval to any person or entity, including us, to market and commercialize therapeutics using our novel and unprecedented iADC or ADC2 technology. We may never receive approval to market and commercialize any potential iADC or ADC2 product candidate. If we uncover any previously unknown risks related to our iADC and ADC2 technology, or if we experience unanticipated or unsolvable problems or delays in developing our iADC or ADC2 product candidates, we may be unable to complete our preclinical studies and clinical trials, meet the obligations of our collaboration and license agreements or commercialize our product candidates on a timely or profitable basis. If serious adverse events or unacceptable side effects are observed in preclinical studies or clinical trials of a product candidate based on our iADC or ADC2 technology, or if iADCs or ADC2s were shown to have limited efficacy, our ability to develop other product candidates based on our iADC or ADC2 technology would be adversely affected. We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of our product candidates using our XpressCF ® and XpressCF ® platforms. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our XpressCF ® and XpressCF ® platforms and resulting product candidates. Since 2014, we have entered into **several** collaborations ~~with Astellas Pharma Inc., or Astellas, Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc., or Merck, Celgene Corporation, or Celgene, a wholly owned subsidiary of Bristol Myers Squibb Company, or BMS, Merck KGaA, Darmstadt Germany (operating in the United States under the name " EMD Serono ", the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US), BioNova Pharmaceuticals Limited, or BioNova, and Tasly Biopharmaceuticals Co., Ltd, or Tasly,~~ to develop and commercialize certain cancer and other therapeutics. Our XpressCF ® and XpressCF ® platforms have also supported a spin- out company, Vaxcyte Inc., focused on discovery and development of vaccines for the treatment and prophylaxis of infectious disease. In addition, we may in the future seek third-party collaborators for research, development and commercialization of other therapeutic technologies or product candidates. Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. With respect to our existing collaboration agreements, and what we expect will be the case with any future collaboration agreements, we have and would expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates currently pose, and will continue to pose, the following risks to us: • collaborators have significant discretion in determining the efforts and resources that they will apply to these 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 preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities ~~, for example, recently, EMD Serono decided to close the Phase 1a trial of M1231 in patients with solid tumors and not initiate a previously planned expansion study. EMD Serono stated that the decision was based on strategic portfolio considerations~~ ; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products; • 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; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and • collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. Moreover, if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects. To date, no product developed on..... associated with manufacturing our development products. Our existing collaborations with Astellas, Merck, ~~BMS, EMD Serono,~~ Vaxcyte ~~, BioNova~~ and Tasly are important to our business. If our collaborators cease development efforts under our existing or future collaboration agreements, fail to fulfill their contract obligations, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements. We have entered into collaborations with other biotechnology companies to develop or commercialize several of our product candidates, and such collaborations currently represent a significant portion of our product pipeline and discovery and preclinical programs. A substantial portion of our revenue to date has been derived from our ~~existing collaboration~~ **collaborations** ~~agreements with Astellas, Merck, BMS, EMD Serono, Vaxcyte, BioNova, and Tasly~~ , and a significant portion of our future revenue and cash resources is expected to be derived from **some of** these agreements **, our royalty monetization agreement, or the Purchase Agreement, with an affiliate of Blackstone Life Sciences, or Blackstone,** or other similar agreements into which we may enter in the future. Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development and other services and product supply, and the achievement of milestones, contingent payments and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates, achieve milestones or earn contingent payments under our collaboration agreements **or royalty monetization agreement** , future revenue and cash resources will be substantially less than expected. We are unable to predict the success of our collaborations and we may not realize the anticipated benefits of our strategic collaborations. Our collaborators have discretion in determining and directing the efforts and resources, including the ability to discontinue all efforts and resources, they apply to the development and, if approval is obtained, commercialization and marketing of the product candidates covered by such collaborations. As a result, our collaborators may elect to de- prioritize our programs, change their strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. For example, ~~recently, each of~~ EMD Serono ~~decided to close the Phase 1a trial of M1231 in patients with solid tumors~~ and **BMS elected** not **to continue the development of** ~~initiate a previously planned expansion study. EMD Serono stated that the~~ **their** ~~decision was~~ **licensed candidates** based on strategic portfolio considerations ~~. BMS advanced a collaboration program, CC-99712, an ADC targeting B- cell maturation antigen, or BCMA, for the treatment of multiple myeloma, into a Phase 1 clinical trial in the third quarter of 2019. BMS has worldwide development and commercialization rights with respect to this BCMA ADC. Additionally, Merck initiated patient dosing in a Phase 1 clinical trial for MK- 1484, a cytokine derivative of IL- 2 discovered and developed under our collaboration, in July 2022. Merck has worldwide rights to MK- 1484 and sole discretion in the clinical development and commercialization for this product candidate. In December 2021, Merck did not extend the research term for another target program of the collaboration and that program reverted to us~~ . Our collaborators may have other marketed products and product candidates under collaboration with other companies, including some of our competitors, and their corporate objectives may not be consistent with our best interests. Our collaborators may also be unsuccessful in developing or commercializing our products. If our collaborations are unsuccessful, our business, financial condition, results of operations and prospects could be adversely affected. Our collaborators may fail to live up to the terms of their agreements with us, which would require us to seek to enforce our agreements in accordance with the dispute resolution procedures set forth therein. These procedures may require us to engage in litigation or arbitration to enforce our rights, which can be expensive, time- consuming and distracting to our management and Board of Directors. Further, the type and timing of resolution of such disputes are difficult to predict; and there is the potential that we could fail to enforce our rights either in part or in whole. Lastly, even if we successfully enforce our rights under our agreements with our collaborators, there is the possibility that we could fail to recover our expectancy following the litigation or arbitration, particularly for collaborators that are not subject to the jurisdiction of U. S. courts. In addition, ~~any~~ **from time to time we may have disputes with our collaborators. Any** dispute or litigation proceedings we may have with our collaborators ~~in the future~~ could delay development programs, reduce or eliminate potential milestone or other payments, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense. ~~For example, in February 2022, Tasly indicated to us that it would like to discuss and renegotiate the terms of the Tasly License Agreement; and in April 2022, we entered into an amendment to the Tasly License Agreement amending the initial payment and certain milestone payments. If we encounter similar situations with Tasly or other collaboration partners, we may fail to recognize the expected future revenue and may be unable to collaborate under the terms of the applicable arrangement.~~ Moreover, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects. We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely

affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management. From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases **or sales** and out- or in- licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time- consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations, or the collaborator terminates the collaboration. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. **Additionally, antitrust or other competition laws, including increased enforcement within the United States in the healthcare space, may also limit our ability to enter into collaborations with certain businesses or to fully realize the benefits of strategic transactions.** Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner' s evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership, without regard to the merits of the challenge, and industry and market conditions generally. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets due to an inability to successfully integrate them with our existing technologies and may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non- recurring or other charges, increase our near- and long- term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management' s time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write- downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. ~~Also, such strategic alliance, joint venture or acquisition may be prohibited. For example, our Loan and Security Agreement, in the absence of the related lenders' prior written consent, restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest.~~ Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market **.** To date,no product developed on a cell- free manufacturing platform has received approval from the FDA,so the requirements for the manufacturing of products using our XpressCF ® and XpressCF ® platforms are uncertain.We have invested in our own current Good Manufacturing Practices,or cGMP,compliant manufacturing facility in San Carlos,California.In this facility,we are developing and implementing novel,proprietary cell- free production technologies to supply our planned preclinical and clinical trials.However,before we may initiate a clinical trial or commercialize any of our product candidates,we must demonstrate to the FDA that the chemistry,manufacturing and controls for our product candidates meet applicable requirements,and in the European Union,or EU,a manufacturing authorization must be obtained from the appropriate EU regulatory authorities.The FDA has allowed ~~Phase 1~~ clinical trial use of our product ~~candidates~~ **candidate** luvelta ~~and STRO- 001,and our partner BMS' s CC- 99712 product candidate,and our partner EMD Serono' s M1231 product candidate~~ ,and our partner Merck' s MK- 1484 product candidate,portions of which are manufactured in our San Carlos manufacturing facility;however,because no product manufactured on a cell- free manufacturing platform has yet been approved in the United States,there is no manufacturing facility that has demonstrated the ability to comply with FDA requirements for later stage clinical development or commercialization,and,therefore,the time frame for demonstrating compliance to the FDA' s satisfaction is uncertain.Delays in establishing that our manufacturing process and facility comply with cGMPs or disruptions in our manufacturing processes,implementation of novel in- house technologies or scale- up activities,may delay or disrupt our development efforts.We ~~expect that~~ **have ongoing technology transfers to enable large scale manufacture of extract and the reagents necessary to manufacture our products using our XpressCF ® and XpressCF ® platforms.These large scale technology transfers may fail or be delayed,resulting in impacts to our** development **timelines and the costs associated** ~~of our own manufacturing facility will provide us~~ with **manufacturing our development products** ~~enhanced control of material supply for preclinical studies,clinical trials and the commercial market,~~ . We expect to rely on third parties to conduct certain of our preclinical studies or clinical trials. If those third parties do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with potentially material and adverse

effects on our business, financial condition, results of operations and prospects. We **do not** have **the ability to independently conduct all aspects of our preclinical testing or clinical trials ourselves. We have accordingly** relied in some cases and intend to rely in the future on third- party clinical investigators, clinical research organizations, or CROs, clinical data management organizations and consultants to assist or provide the design, conduct, supervision and monitoring of preclinical studies and clinical trials of our product candidates. Because we intend to rely on these third parties and will not have the ability to conduct all preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful. If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires preclinical studies to be conducted in accordance with good laboratory practices and clinical trials to be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations and prospects. ~~If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other manufacturing or supply difficulties, our business may be adversely affected. The manufacture of certain of our product candidates requires the timely delivery of sufficient amounts of raw and intermediate materials. We work closely with our suppliers to ensure the continuity of supply, but cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier. While we believe that alternative sources of supply exist where we rely on sole supplier relationships, there can be no assurance that we will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product candidates in a timely or cost- effective manner. We currently manufacture a portion of our product candidates internally and also rely on third- party manufacturing and supply partners to supply components of our product candidates and materials used to manufacture our product candidates.~~ Our inability to manufacture sufficient quantities of our 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 and adversely affect our business. Manufacturing is a vital component of our business strategy. To ensure timely and consistent product supply **,** we currently use a hybrid product supply approach wherein certain elements of our product candidates are manufactured internally at our manufacturing facilities in San Carlos, California, and other elements **, including raw and intermediate materials,** are manufactured at qualified third- party CMOs. Since our own manufacturing facilities may be limited or unable to manufacture certain of our preclinical and clinical trial product materials and supplies, we rely on third- party contract manufacturers to manufacture such clinical trial product materials and supplies for our or our collaborator' s needs. For example, we have entered into a manufacturing agreement with EMD Millipore Corporation to ~~provide manufacturing services for certain linker- warhead materials used in our STRO- 001 product candidate and to~~ perform conjugation of the applicable linker- warhead with the antibody component of our luvelta and STRO- ~~001~~ **003** product candidates. We have also entered into agreements with Capua Bioservices, S. p. A. and with AGC Biologics GmbH for the manufacture of certain reagents used in the manufacture of our products with our XpressCF ® and XpressCF ® platforms. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices **. Further, while efforts are made to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier** . In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, replacement of a manufacturer may require a technology transfer to the new manufacturer, which involves technical risk that the transfer may not succeed or may be delayed, and which can incur significant costs. The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. If we or our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on our or their manufacturing facilities for the manufacture of elements of our product candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product

candidates may be unique or proprietary to the original manufacturer and we may have difficulty applying such skills or technology ourselves, or in transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. We expect to continue to rely on third- party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third- party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party' s failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including: • an inability to initiate or continue clinical trials of product candidates under development; • delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates; • loss of an existing or future collaborator; • losses resulting from an inability to utilize reserved manufacturing capacity because of delays or difficulties encountered in the supply chain; • subjecting third- party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities; • requirements to cease distribution or to recall batches of our product candidates; and • in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products. Additionally, we and our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments, or epidemics, pandemics, or contagious diseases ~~, such as the COVID- 19 pandemic,~~ or failures or delays in our manufacturing supply chain. For example, restrictions on travel imposed by governments, including China, or restrictions on person- in- plant permissions imposed by our contract manufacturers may limit the ability of our subject matter experts to visit our manufacturers and assist with technology transfers. If we or our contract manufacturers were to encounter interruptions from any of these events or other unforeseen events, our ability to provide our product candidates to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized. We, or third- party manufacturers, may be unable to successfully scale- up manufacturing of our product candidates or materials used to manufacture components of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any. In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale- up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates, or materials used in manufacturing components of our product candidates, in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. Scaling up a biologic manufacturing process is a difficult and uncertain task, and we may not be successful in transferring our production system or our third- party manufacturers may not have the necessary capabilities to complete the implementation and development process. If we are unable to adequately validate or scale- up the manufacturing process at our own manufacturing facilities or those of our current manufacturers, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale- up the manufacturing process for our product candidates at our manufacturing facility or with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us. The manufacture of biologics is complex and we or our third- party manufacturers may encounter difficulties in production. If we or any of our third- party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our products for patients, if approved, could be delayed or stopped. Our product candidates are considered to be biologics and the process of manufacturing biologics and materials used to manufacture components of our products can be complex, time- consuming, highly regulated and subject to multiple risks. We and our contract manufacturers must comply with cGMPs, regulations and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. To date, we and our contract manufacturers have limited experience in the manufacturing of cGMP batches of our product candidates and materials used to manufacture components of our product candidates. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our manufacturing facilities or those of our third- party manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our manufacturing facilities or those of our third- party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance. In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with cGMPs, lot consistency, timely availability of raw materials and other technical challenges.

Even if we or our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects. We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. If we or our third- party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products, such as epidemics, pandemics or contagious diseases, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write- offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, financial condition, results of operations and prospects. As part of our process development efforts, 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, 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. We may not be successful in our efforts to use our XpressCF ® and XpressCF ® platforms to expand our pipeline of product candidates and develop marketable products. The success of our business depends in large part upon our ability to identify, develop and commercialize products based on our XpressCF ® and XpressCF ® platforms. Luvelta is our most advanced clinical stage program ~~and STRO- 001 is our next most advanced clinical stage program~~ , and our preclinical and research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected product candidates. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. **For example, in June 2023, we announced our Purchase Agreement with Blackstone.** Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for our product candidates could harm our drug development strategy and operational results. If companion diagnostics are developed in conjunction with clinical programs, the FDA may require regulatory approval of a companion diagnostic as a condition to approval of the product candidate. For example, as we are developing luvelta for treatment of patients having ovarian cancer with elevated FolRα expression levels, we are likely to be required to obtain FDA approval or clearance of a companion diagnostic, concurrent with approval of luvelta, to test for elevated FolRα expression. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. We have entered into an agreement to develop diagnostic assays suitable for use as a companion diagnostic for luvelta. Companion diagnostics are subject to regulation by the FDA and foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization. **We** ~~Similarly, if we use a diagnostic test to determine which patients are most likely to benefit from STRO- 001 for the treatment of multiple myeloma and NHL by designing our pivotal trial or trials of STRO- 001 in that indication to require that clinical trial patients have elevated CD74 expression as a criterion for enrollment, then we will likely be required to obtain FDA approval or clearance of a companion diagnostic, concurrent with approval of STRO- 001, to test for elevated CD74 expression; we~~ may also be required to demonstrate to the FDA the predictive utility of the companion diagnostic — namely, that the diagnostic selects for patients in whom the biologic therapy will be effective or more effective compared to patients not selected for by the

diagnostic ~~. In addition, our partner BMS may be required to develop and obtain regulatory clearance for a companion diagnostic to assess BCMA expression in patients in connection with their development of CC- 99712~~ . If we or our collaborators, or any third party, are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so: • the development of our product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our planned clinical trials; • our product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and • we may not realize the full commercial potential of any product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific genetic alterations targeted by our product candidates. In addition, although we believe genetic testing is becoming more prevalent in the diagnosis and treatment of various diseases and conditions, our product candidates may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic or the need to complete additional procedures to identify genetic markers prior to administering our product candidates. If any of these events were to occur, our business would be harmed, possibly materially. We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected. The development and commercialization of drugs and therapeutic biologics is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources **, including financial, technical, manufacturing, marketing, sales, supply, human resources, or general experience** than we do and we may not be able to successfully compete. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as with technologies and product candidates being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel technology platforms, that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are trying, or may try, to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and antibody and immunoregulatory therapeutics fields. While we believe that our XpressCF ® and XpressCF ® platforms, associated intellectual property and our scientific and technical know- how give us a competitive advantage in this space, competition from many sources exists or may arise in the future. Our competitors include larger and ~~better~~ **well-** funded biopharmaceutical, biotechnological and therapeutics companies, including **large and specialty** companies focused on cancer immunotherapies ~~, such as AstraZeneca PLC, BMS, GlaxoSmithKline PLC, Johnson & Johnson, Merck Sharp & Dohme LLC, Novartis AG, Pfizer Inc., or Pfizer, Roche Holding Ltd, Sanofi S. A.,~~ and ~~companies focused on~~ ADCs ~~, such as BMS, Pfizer, GlaxoSmithKline PLC, Daiichi Sankyo Company, Limited, Eisai, Co., Ltd., ImmunoGen, Inc., Eli Lilly & Company, Pfizer, Exelixis, Inc., Seagen, Inc., Astellas Pharma Inc., Genentech, Inc., or Genentech, Gilead Sciences Inc., Mersana Therapeutics, Inc., and ADC Therapeutics SA~~ , as well as numerous small **and mid-cap** companies. Moreover, we also compete with current and future therapeutics developed at **research- stage biotechnology companies,** universities and other research institutions. We are aware of several companies that are developing ADCs, cytokine derivatives, bispecific antibodies and cancer immunotherapies, including companies developing ADCs directed to the same target as luvelta. For example, Immunogen recently received approval for a folate receptor α targeted ADC, ~~ELAHERE ™~~ **mirvetuximab soravtansine (Elahere ®)** . ~~BMS~~ **In addition, large pharmaceutical companies** and ~~Eisai~~ **smaller biotechnology companies** are ~~also collaborating on development~~ **developing other** ~~of a similarly targeted ADC~~ **ADCs** ~~, known as MORAb~~ **; and we anticipate more FolRα** - ~~202~~ **targeting ADCs and other potential FolRα- targeting modalities to be evaluated in the clinic in the coming years. Further, other companies may develop ADCs targeting receptors other than folate receptor α for the treatment of the same indications for which we are developing luvelta** . Many of these companies are well- capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies compete with us in recruiting scientific and managerial talent. Our success will depend partially 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 are safer, more effective, or less expensive than the therapeutics we develop. If our most advanced product candidates are approved, they will compete with a range of therapeutic treatments that are either in development or currently marketed. Currently marketed oncology therapeutics include a range of biologic modalities with the top selling products by class spanning tumor targeting monoclonal antibodies, ~~such as Johnson & Johnson' s Darzalex;~~ to ADCs, ~~such as Genentech' s Kadcyla;~~ to immune checkpoint inhibitors, ~~such as Merck' s Keytruda;~~ to T cell- engager immunotherapies, ~~such as Amgen, Inc.' s Blincyto;~~ and to CAR- T cell therapies ~~, such as Gilead' s Yescarta~~ . In addition, numerous compounds are in clinical development for cancer treatment. The clinical development pipeline for cancer includes small molecules, antibodies, vaccines, cell therapies and immunotherapies from a variety of companies and institutions. **Further** ~~Many of our competitors~~ , **if** ~~either alone or with strategic partners, have significantly greater financial, technical, manufacturing, marketing, sales, supply, and human resources or experience than we have. 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. 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~~ . Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan. We are highly dependent on the research and development, clinical development, manufacturing, and business development expertise of our management team, advisors and other specialized personnel. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our product candidates and XpressCF ® and XpressCF ® platform technologies and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. ~~If~~ **Should our competitors recruit our key employees, our level of expertise and ability to execute our business plan would be negatively impacted. Further, if** we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can discover and develop product candidates will be limited, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations. As of December 31, ~~2022~~ **2023** , we had ~~278~~ **302** full- time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development and began our first clinical ~~trials~~ **trial** ~~for our first two product candidates~~ in 2018 ~~and 2019~~ . As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects ~~. For example, the COVID- 19 pandemic has resulted in a significant percentage of our employees working remotely from time to time, which has amplified certain risks to our business. For example, the increase in remote work has increased demand on our information technology resources and systems, increased phishing and other malicious activity as cybercriminals try to exploit the uncertainty surrounding the COVID- 19 pandemic, which has led to an increase in the number of points of potential exposure, such as laptops and mobile devices, that need to be secured. Any failure to effectively manage these risks, including to timely identify and appropriately respond to any security incidents, may adversely affect our business. The COVID- 19 pandemic has also had an adverse effect on our ability to attract, recruit, interview and hire at the pace we would typically expect to support our rapidly expanding operations. Additionally, we have incurred increased costs as a result of COVID- 19, including increased expenses to implement additional measures to ensure the health and safety of our workforce, such as reimbursing for periodic COVID- 19 testing and providing face masks~~ . If any of our product candidates are approved for marketing and commercialization and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to commercialize successfully any such future products. We currently have limited sales, marketing and distribution capabilities or experience. If any of our product candidates are approved, we will need to develop additional internal sales, marketing and distribution capabilities to commercialize such products, which would be expensive and time consuming, or enter into collaborations with third parties to perform these services. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products or decide to co- promote products with collaborators, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third- party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business, financial condition, results of operations and prospects could be materially and adversely affected. Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market ~~,~~ and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and

distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and do not receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be materially and adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries. Price controls imposed in **either the U. S. or** foreign markets may adversely affect our future profitability. ~~In affect our future profitability.~~ Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products,which has resulted in recent Executive Orders,several Congressional inquiries and proposed and enacted federal and state legislation designed to,among other things,bring more transparency to product pricing,review the relationship between pricing and manufacturer patient programs,and reform government program reimbursement methodologies for drug products.Current and future presidential budget proposals and future legislation may contain further drug price control measures that could be enacted.Congress and current and future U.S.presidential administrations may continue to seek new legislative and / or administrative measures to control drug costs.At the state level,legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing,including price or patient reimbursement constraints,discounts,restrictions on certain product access and marketing cost disclosure and transparency measures,and,in some cases,designed to encourage importation from other countries and bulk purchasing.If such pricing controls are enacted and are set at unsatisfactory levels,our business,financial condition,results of operations and prospects could be materially and adversely **affected.Additionally,in** some countries, particularly member states of the EU, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of our therapeutic candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations and prospects could be materially and adversely affected. Price controls imposed in the U..... could be materially and adversely affected. Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects. As we are conducting clinical trials of our product candidates, we may be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management' s time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. While we currently have product liability insurance that we believe is appropriate for our stage of development, we may need to obtain higher levels prior to later stages of clinical development or marketing any of our product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. As with all companies, we are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, inappropriately share confidential and proprietary information externally, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are

instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm. Moreover, our employees are increasingly utilizing social media tools and our website as a means of communication. Despite our efforts to monitor social media communications, there is risk that the unauthorized use of social media by our employees to communicate about our products or business, or any inadvertent disclosure of material, nonpublic information through these means, may result in violations of applicable laws and regulations, which may give rise to liability and result in harm to our business. In addition, there is also risk of inappropriate disclosure of sensitive information, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse impact on our business, financial condition, results of operations and prospects. We depend on our information technology systems, and any failure of these systems, or those of our CROs, third- party vendors, or other contractors or consultants we may utilize, could harm our business. Security breaches, cyber- attacks, loss of data, and other disruptions could compromise sensitive information related to our business or other personal information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, reputation, results of operations, financial condition and prospects. We collect **, use** and ~~maintain~~ **store** 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. In the ordinary course of our business, we collect, **use,** store and transmit large amounts of confidential information, including intellectual property, proprietary business information health information, and personal information. We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a data security incident (which may include, for example: data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or information technology incidents caused by threat actors, technological vulnerabilities or human error), 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. 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 confidential information **subject to contractual protections** . Our internal information technology systems and infrastructure, and those of our current and any future collaborators, CROs, third- party vendors, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber- attacks or cyber- intrusions over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a **formal** 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 **. For example, targeted deep fakes supported by sophisticated AI tools and other forms of impersonation of our executives are becoming increasingly prevalent** . 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 of confidential information or other intellectual property. The costs to us or our CROs or other contractors or consultants we may utilize to mitigate a data security incident and security vulnerabilities could be significant, and while we have implemented security measures designed 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. We have incurred successful phishing attempts in the past, although we believe that these attempts were detected and neutralized without any compromise to our data and prior to any significant impact to our business. We have also implemented measures to prevent such attacks, but we may still be subject to similar attacks in the future. We are also aware of publicly disclosed security breaches at certain third ~~-~~-parties on which we rely ~~, although we have not been informed of any resulting breach to our data~~ . If such an event were to occur, whether to us or a third ~~-~~-party on which we rely, 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. Further, if we are unable to generate or maintain access to essential patient samples or data for our research ~~and~~ **,** development **,** and manufacturing activities for our programs, our business could be materially adversely affected. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. Such a breach may require **formal** notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, regulations promulgated by the Federal Trade Commission and state breach notification laws. We also may be subject to ~~European~~ **global** privacy laws, such as ~~the~~ **Europe' s** General Data Protection Regulation, or GDPR. We would also be exposed to a risk of loss or litigation and potential liability under laws, regulations and contracts that protect the privacy and security of personal information that may result in regulatory scrutiny, fines, private right of action settlements, and other consequences. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time- intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight. Our failure to comply with such laws or to adequately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, member base and revenue. Our information

technology systems could face serious disruptions that could adversely affect our business. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines, and connection to the Internet, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause interruptions and delays in our research and development and manufacturing work. **In addition, some of our employees work remotely from time to time, which presents certain risks to our business. For example, remote work presents significant demands on our information technology resources and systems and can be at risk for phishing and other malicious activity, which can result in an increase to the number of points of potential exposure, such as laptops and mobile devices, that need to be secured. Any failure to effectively manage these risks, including to timely identify and appropriately respond to any security incidents, may adversely affect our business. In our ongoing efforts to innovate and optimize operational efficiency, we have integrated artificial intelligence, or AI, into various aspects of our workplace. For example, we are implementing AI machine learning for email behavioral monitoring. While AI presents opportunities for enhanced productivity and innovation, it also introduces inherent risks, including legal and regulatory, that could adversely impact our business and reputation. Proper use of AI can lead to improved decision- making, cost reduction, and competitive advantage. However, improper use, including algorithmic biases, ethical considerations, data privacy issues, unknown or zero- day software vulnerabilities, and potential regulatory non- compliance, could result in reputational damage, legal liabilities, and financial losses.** The ~~terms of~~ **rapidly evolving regulatory landscape surrounding AI also poses a risk, as new laws and regulations could impose additional compliance burdens, resulting in increased operational costs. We are committed to implementing robust governance and control mechanisms to mitigate these risks, but there can be no assurance that such measures will adequately prevent** ~~our~~ - **or** ~~Loan~~ **mitigate the adverse effects that the integration** and ~~Security Agreement require us~~ **use of AI may have** ~~to meet certain covenants and place restrictions~~ on ~~our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. The Loan and Security Agreement is secured by a lien covering all of our assets, excluding our intellectual property. Subject to the terms of the Loan and Security Agreement, we have the option to prepay all, but not less than all, of the amounts borrowed under the Loan and Security Agreement, subject to certain penalty payments, prior to the March 1, 2024, maturity date, at which time all amounts borrowed will be due and payable. The Loan and Security Agreement contains customary affirmative and negative covenants, indemnification provisions and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain certain intellectual property rights. The negative covenants include, among others, restrictions on transferring or licensing our assets, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on our assets, in each case subject to customary exceptions. If we default under the Loan and Security Agreement, the lenders will be able to declare all obligations immediately due and payable and take control of our collateral, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. The Loan and Security Agreement previously included a covenant requiring us to keep substantially all of our cash and investments with SVB, the substantial majority of which was held in a custodial account with another institution, for which SVB Asset Management was the advisor. In March 2023, we amended our Loan and Security Agreement to allow us to hold cash and investments at multiple financial institutions and we began the process of moving cash and investments into accounts at other financial institutions. Further, if we are liquidated, the rights of Oxford and SVB to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford, acting as collateral agent for the lenders, could declare a default under the Loan and Security Agreement upon the occurrence of any event that Oxford and SVB interpret as a material adverse change as defined under the Loan and Security Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the collateral agent of an event of default could significantly harm~~ our business, financial condition, **and** results of operations ~~and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility~~ . If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be affected adversely. Our research, development and manufacturing involve the use of hazardous chemicals and materials, including radioactive materials. We maintain quantities of various flammable and toxic chemicals in our facilities in South San Francisco and San Carlos, California that are required for our research, development and manufacturing activities. We **generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We and our third- party contractors** are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous chemicals and materials. We believe our **and our third- party contractors'** procedures for storing, handling and disposing these materials in our South San Francisco and San Carlos facilities comply with the relevant guidelines of the two municipalities, the county of San Mateo, the state of California and the Occupational Safety and Health Administration of the U. S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, including employee and contractor training and procedures regarding safe handling and disposal, the risk of accidental or mistaken contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial **and exceed any available insurance** . We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood- borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials or from other hazards potentially present in our workplaces, such as high voltage electricity, process steam or

other hot material, liquid nitrogen or other cold material, materials stored under pressure, laboratory instruments that incorporate powerful lasers or magnets, sonic resonance, heavy machinery, and the like, this insurance may not provide adequate coverage against potential liabilities. While we maintain pollution legal liability insurance for our manufacturing facility in San Carlos, California, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials in our other locations. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future **and existing laws and regulations could become more stringent** . ~~We~~ **Further, we** may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations **. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations. U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, CMOs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or making or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We also expect our non- U. S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and / or to obtain necessary permits, licenses, patent registrations and other marketing authorizations. We can be held liable for corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences** . Our current operations are in two cities in the San Francisco Bay Area, and we, or the third parties upon whom we depend, may be adversely affected by earthquakes, other natural disasters, pandemics ~~, including any significant resurgence of the COVID- 19 pandemic,~~ or other catastrophic events and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our current operations are located in our facilities in South San Francisco and San Carlos, California. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, epidemic, pandemic or contagious disease ~~, including any significant resurgence of the COVID- 19 pandemic~~ , power shortage, telecommunication failure or other natural or man- made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third- party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, epidemics, pandemics or contagious diseases, or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage, epidemics, pandemics or contagious disease, or other events occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research or manufacturing facilities or the manufacturing facilities of our third- party contract manufacturers, 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 may prove inadequate 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 could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. In addition, the long- term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters. If our facilities, or the manufacturing facilities of our third- party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. **Further, many of our employees conduct business outside of our leased or owned facilities and these locations may be subject to additional security risks outside of our control.** Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flows, financial condition or results of operations. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the 2017 Tax Act, enacted many significant changes to the U. S. tax laws. **Beginning in 2022,** ~~Future guidance from the Internal Revenue Service and other tax authorities with respect to~~ the 2017 Tax Act ~~may affect us,~~ **eliminates the option to currently deduct research** and ~~certain aspects of~~ **development expenditures and requires taxpayers to capitalize and amortize U. S. based and non- U. S. based research and development expenditures over five and fifteen years, respectively, pursuant to IRC Section 174. Although** ~~the~~ **there** ~~2017 Tax Act may~~ **have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will** be repealed or **otherwise** modified ~~in future legislation~~ . **We also cannot predict whether, when, in what form,** ~~For~~ **or** ~~example~~ **with what effective dates** , **tax laws** ~~the Coronavirus Aid~~ , ~~Relief~~ **regulations and rulings may be enacted** , **promulgated or issued, which could**

result in ~~and -~~ **an increase in** ~~Economic Security Act, or~~ **our or our stockholders' tax liability or require changes in** the ~~CARES Act, modified certain provisions~~ **manner in which we operate in order to minimize or mitigate any adverse effects** of ~~the 2017 Tax Act~~ **changes in tax law** . Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, ~~and the deductibility of expenses under the 2017 Tax Act~~ or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense. Our ability to use net operating loss carryforwards to offset taxable income could be limited. **Under** ~~We plan to use our~~ current **law** ~~year operating losses to offset taxable income from any revenue generated from operations~~ , ~~including revenue from licensing and collaboration agreements and other similar transactions. To the extent that~~ our ~~taxable income exceeds any current year operating losses, we plan to use our net operating loss carryforwards from prior taxable years to offset income that would otherwise be taxable. Our~~ net operating loss carryforwards generated in tax years ending on or prior to December 31, 2017, are ~~only~~ permitted to be carried forward for 20 years **and** ~~under applicable U. S. tax law. Under the 2017 Tax Act, as modified by the CARES Act,~~ our federal net operating losses generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses, is limited to 80 % of taxable income ~~. It is~~ **(without regard to** ~~uncertain~~ -- **certain deductions)** ~~if and to what extent various states will conform to the 2017 Tax Act or the CARES Act~~ . In addition, under Section 382 of the U. S. Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if we experience an " ownership change " which is generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, our ability to use our pre- change net operating loss carryforwards to offset our post- change income may be limited. Based on Section 382 studies performed for certain prior periods, ~~it is more likely than not that~~ we experienced an ownership change on November 20, 2019 **and December 31, 2022** , which imposed limitations on the use of our net operating losses arising before that date. In addition, we may have experienced other ownership changes in the past and may also experience ownership changes in the future as a result of equity offerings or other shifts in our stock ownership, some of which are outside our control. As a result, our use of federal NOL carryforwards could be limited. State net operating loss carryforwards may be similarly limited. In addition, 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. Any such limitations may result in greater tax liabilities than we would incur in the absence of such limitations and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows. Our investment in Vaxcyte is subject to risk As of December 31, ~~2022~~ **2023** , we held Vaxcyte common stock with a fair value of $ ~~32~~ **41** . ~~0~~ **9** million. Vaxcyte common stock is publicly traded and therefore subject to the various risk factors associated with any publicly traded company, including risks associated with Vaxcyte' s business, its business outlook, cash flow requirements and financial performance, the state of the market and the general economic climate, including the impact of **health** ~~the COVID- 19 pandemic~~ **pandemics** , ~~rising~~ **regional geopolitical conflicts, changes in** interest rates, ~~and~~ inflation **, potential uncertainty with respect to the debt ceiling and potential government shutdowns related thereto** . Vaxcyte common stock has been subject to substantial volatility, and the change in fair value of our interests in Vaxcyte will materially impact our reported net income or net loss in our financial statements. Our cash and investments could be adversely affected if the financial institutions in which we hold our cash and investments fail. We regularly maintain cash balances at third- party financial institutions ~~, including with SVB,~~ in excess of the FDIC insurance limit and similar regulatory insurance limits outside the United States **and governments may not guarantee all depositors if such financial institutions were to fail, as the U. S. government did in 2023 with Silicon Valley Bank depositors, in the event of further bank closures and continued instability in the global banking system. Any future adverse developments in the global banking system could directly or indirectly negatively impact our business, financial condition, results of operations and prospects** . Further, if we enter into a credit, loan or other similar facility with a financial institution, certain covenants included in such facility may require as security that we keep a significant portion of our cash with the institution providing such facility. If a depository institution where we maintain deposits fails or is subject to adverse conditions in the financial or credit markets, we may not be able to recover all, if any, of our deposits, which could adversely impact our operating liquidity and financial performance. Our financial results may be adversely affected by changes in accounting principles generally accepted in the United States. Generally accepted accounting principles in the United States, or U. S. GAAP, are subject to interpretation by the Financial Accounting Standards Board, or the FASB, the American Institute of Certified Public Accountants, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. For example, in May 2014, the FASB issued accounting standards update No. 2014- 09 (Topic 606), Revenue from Contracts with Customers, which supersedes nearly all existing revenue recognition guidance under U. S. GAAP. We adopted this new accounting standard as of January 1, 2019. Any difficulties in implementing this guidance could cause us to fail to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. Additionally, the implementation of this guidance or a change in other principles or interpretations could have a significant effect on our financial results, and could affect the reporting of transactions completed before the announcement of a change. Furthermore, we have adopted Topic 606 through the modified retrospective method. This will impact the comparability of our financial results, which might lead investors to draw incorrect conclusions that could harm investor interest in holding or purchasing our equity. Risks Related to Intellectual Property If we are not able to obtain, maintain and enforce sufficient patent and other intellectual property protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected. Our success depends in part on our, our licensor' s and our collaborators' ability to obtain and maintain patents and other forms of intellectual property rights, including in- licenses of intellectual property rights of others, for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. We, our licensors and collaborators may not be able to apply for patents on certain aspects of our product candidates in a timely fashion or at all ~~, including delays as~~

~~a result of the COVID- 19 pandemic impacting our or our licensors' operations~~ . Further, we, our licensors and collaborators may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we, our licensors and collaborators will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is also possible that we, our licensors, and our collaborators will fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently- developed invention. Such competitor' s patent application may pose obstacles to our ability to obtain or limit the scope of patent protection we may obtain. We may not have the right to control the preparation, filing and prosecution of all patent applications that we license from third parties, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our licensors or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. Also, although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we, our licensors or collaborators were the first to make the inventions claimed in our patents or pending patent applications, or were the first to file for patent protection of such inventions, or if such patents rights may otherwise become invalid. Composition of matter patents for biological and pharmaceutical therapeutic candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our therapeutic candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our therapeutics for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products " off- label. " Although off- label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. Our existing issued and granted patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market. The U. S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. 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. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. While we will endeavor to try to protect our product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and sometimes unpredictable. 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. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, there can be no assurance that: • others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license; • we or our licensors, or our existing or future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license; • we or our licensors, or our existing or future collaborators are the first to file patent applications covering certain aspects of our inventions; • others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed; • any issued patents that we own or have licensed will provide us with any competitive advantages, or will not be challenged by third parties; • we may develop additional proprietary technologies that are patentable; • the patents of others will

not have a material or adverse effect on our business, financial condition, results of operations and prospects; and • our competitors **may** ~~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. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. In addition, our in- licensed patents may be subject to a reservation of rights by the licensor, its affiliates and one or more third parties. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non- exclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties or allow third parties to use our licensed technology. The government can also exercise its march- in rights if it determines that action is necessary because we fail to achieve practical application of the government- funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U. S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent protection for certain aspects of our product candidates, we also consider trade secrets, including confidential and unpatented know- how important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know- how, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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 in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed which could have a material and adverse effect on our business, financial condition, results of operations and prospects. Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing our products. Therapeutics in oncology or other disease areas developed in cell- free- based synthesis systems are a relatively new scientific field. We have obtained grants and issuances of, and have obtained a license from a third party on an exclusive basis to, patents related to our proprietary XpressCF ® and XpressCF ® platforms. The issued patents and pending patent applications in the United States and in key markets around the world that we own or license claim many different methods, compositions and processes relating to the discovery, development, manufacture and commercialization of antibody- based and other therapeutics. As the field of antibody- based therapeutics continues to mature, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete. We may not be able to protect our intellectual property rights throughout the world. Obtaining a valid and enforceable issued or granted patent covering our technology in the United States and worldwide can be extremely costly, and our or our licensors' or collaborators' intellectual property rights may not exist in some countries outside the United States or may be less extensive in some countries than in the United States. In jurisdictions where we or our licensors or collaborators have not obtained patent protection, competitors may seek to use our or their technology to develop their own products and further, may export otherwise infringing products to territories where we or they have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our or our licensors' or collaborators' issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly relating to biopharmaceuticals. This could make it difficult for us or our licensors or collaborators to prevent the infringement of our or their patents or marketing of competing products in violation of our or their proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. We generally file a provisional patent application first (a priority filing) at the USPTO. An international application under the Patent Cooperation Treaty, PCT, is usually filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications

may be filed in the United States, EU, Japan, Australia and Canada and, depending on the individual case, also in any or all of, inter alia, Brazil, China, Hong Kong, India, Israel, Mexico, New Zealand, South Africa, South Korea and other jurisdictions. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that depending on the country, various scopes of patent protection may be granted on the same product candidate or technology. Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia' s invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit- making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors or collaborators encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors or collaborators are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business, financial condition, results of operations and prospects may be adversely affected. ~~No earlier than June 1, 2023,~~ European **patent** applications **now** ~~will soon~~ have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ~~(~~"**, or** UPC ~~)~~. This will be a significant change in European patent practice. As the UPC is a new court system, there is ~~no~~ **very limited** precedent for the court, increasing the uncertainty of any litigation **. Limited information is available to make judgments about advantages and disadvantages of either opting into or remaining out of UPC jurisdiction; either choice may ultimately prove to have significant implications as to cost, enforceability and scope of protection, among other factors, for applicable European patents** . We, our licensors or collaborators, or any future strategic partners may need to resort to litigation to protect or enforce our patents or other proprietary rights, all of which could be costly, time consuming, delay or prevent the development and commercialization of our product candidates, or put our patents and other proprietary rights at risk. Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that an individual connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to 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. 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. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our therapeutics. As the biopharmaceutical 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. There can be no assurance that

our operations do not, or will not in the future, infringe existing or future third- party patents. Identification of third- party patent rights that may be relevant to our operations 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. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our therapeutic candidates in any jurisdiction. Numerous U. S. and foreign patents and pending patent applications exist in our market that are owned by 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 therapeutics. 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 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 U. S. 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 therapeutics or the use of our therapeutics. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent 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 therapeutics. 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. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our therapeutics are not covered by a third- party patent or may incorrectly predict whether a third- party' s pending 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. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms. We, our licensors or collaborators, or any future strategic partners may be subject to third- party claims for infringement or misappropriation of patent or other proprietary rights. 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 and inter partes review proceedings before the USPTO, and corresponding foreign patent offices. For example, one of our European patents related to technology auxiliary to our XpressCF ® platform is involved in an opposition proceeding at the European Patent Office, or EPO, and was revoked by the EPO in 2021. In April 2022, an appeal was filed ~~and oral proceedings~~ **; the process** for ~~the~~ **this** appeal is **ongoing** ~~scheduled for October 27, 2023~~ . This may prevent us from asserting this patent against our competitors practicing otherwise infringing methods in relevant European countries where this patent has been granted. There are many issued and pending patents that might claim aspects of our product candidates and modifications that we may need to apply to our product candidates. There are also many issued patents that claim antibodies, portions of antibodies, cytokines, half- life extending polymers, linkers, cytotoxins, or other warheads that may be relevant for the products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may be delayed or may not be able to market products or perform research and development or other activities covered by these patents which could have a material and adverse effect on our business, financial condition, results of operations and prospects. We are obligated under certain of our license and collaboration agreements to indemnify and hold harmless our licensors or collaborators for damages arising from intellectual property infringement by use. For example, we are obligated under the Stanford Agreement to indemnify and hold harmless Stanford for damages arising from intellectual property infringement by us resulting from exercise of the license from Stanford. If we, our licensors or collaborators, or any future strategic partners are found to infringe a third- party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages, if we are found to have infringed willfully. In addition, we, our licensors or collaborators, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non- exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our

favor, could be substantial, and litigation could divert our management' s attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations. Because the antibody- based therapeutics landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing on third- party rights. There are numerous companies that have pending patent applications and issued patents broadly covering antibodies generally, covering antibodies directed against the same targets as, or targets similar to, those we are pursuing, or covering linkers and cytotoxic warheads similar to those that we are using in our product candidates. For example, we are aware of an issued patent, expected to expire in 2031, that relates to strained alkyne reagents that can be used as synthetic precursors for certain of our linker- warheads. We are ~~also~~ **further** aware of an issued patent **,** expected to expire in ~~2028~~ **2034** , ~~relating to methods for targeting maytansinoids to a selected population of cells with a cell- binding agent conjugated to a maytansinoid with a non- cleavable linker. We are further aware of a published patent application~~ relating to certain conjugates comprising a genus of hemiasterlin derivatives that ~~, if the claims were to issue as they are currently presented to the United States Patent and Trademark Office for examination,~~ may be potentially relevant to products incorporating our hemiasterlin- derived linker- warhead. If any of these patents are valid and not yet expired when, and if, we receive marketing approval for luvelta ~~or STRO- 001~~ , as applicable, we may need to seek a license to one or more of these patents, each of which may not be available on commercially reasonable terms or at all. Failure to receive a license to any of these patents, or other potentially relevant patents currently unknown to us, could delay commercialization of **any or all of** luvelta ~~or~~ **,** STRO- ~~001~~ **003 or STRO- 004** . Our competitive position may suffer if patents issued to third parties or other third- party intellectual property rights cover our products or product candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or product candidates until such patents expire or unless we successfully pursue litigation to nullify or invalidate the third- party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our XpressCF ® and XpressCF ® platforms and related technologies and product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our XpressCF ® and XpressCF ® platforms and related technologies and product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, including potentially treble damages and attorneys' fees for willful infringement, and we may be forced to abandon our product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all. It is also possible that we have failed to identify relevant third- party patents or applications. For example, U. S. applications filed before November 29, 2000, and certain U. S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technologies could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products. Third- party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time- consuming litigation and may be prevented from or experience substantial delays in marketing our products. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could have a material and adverse effect on our business, financial condition, results of operations and prospects. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments 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. Moreover, such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their

greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses. Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and / or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell any future products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. 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 determine currently 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. Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our product candidates, technologies and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights under our collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • the priority of invention of patented technology. In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel. Many of our employees were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs,

our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other 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 have systems in place to remind us to pay these fees, and we employ an outside firm and / or rely on our outside counsel to pay these fees due to non- U. S. patent agencies. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and 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 non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business. Changes in U. S. patent and ex- U. S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the United States or in other ex- U. S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the America Invents Act, enacted within the last several years involves significant changes in patent legislation. The U. S. Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. For example, the decision by the U. S. Supreme Court in Association for Molecular Pathology v. Myriad Genetics, Inc. precludes a claim to a nucleic acid having a stated nucleotide sequence that is identical to a sequence found in nature and unmodified. We currently are not aware of an immediate impact of this decision on our patents or patent applications because we are developing product candidates that contain modifications that we believe are not found in nature. However, this decision has yet to be clearly interpreted by courts and by the USPTO. We cannot assure you that the interpretations of this decision or subsequent rulings will not adversely impact our patents or patent applications. 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 the U. S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, 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 that we might obtain in the future. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Our current or future licensors may have relied on third- party consultants or collaborators or on funds from third parties, such as the U. S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in- licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our 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 or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. Risks Related to Government Regulation Clinical

development involves a lengthy and expensive..... regulatory approval of our product candidates. We and / or our collaborators may be unable to obtain, or may be delayed in obtaining, U. S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates. Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop, either alone or with our collaborators, will obtain the regulatory approvals necessary for us or our existing or future collaborators to begin selling them. Although **some of** our employees have experience in conducting and managing clinical trials from prior employment at other companies, we, as a company, have no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate, and may be further delayed due to one or more temporary federal government shutdowns. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We or our collaborators may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. For example, the Oncology Center of Excellence within the FDA has recently advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate' s dose- response relationship to facilitate optimum dose selection in a target population. Other recent Oncology Center of Excellence initiatives have included Project FrontRunner, a new initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options. We are considering these policy changes as they relate to our programs. **We may also be affected by ex- US regulatory requirements, given that our trials may be conducted globally; current and unforeseen new EU- specific clinical trial conduct regulations, such as IVDR and GDPR, may delay, or increase the difficulty and expense of conducting, our clinical studies.** Given that the product candidates we are developing, either alone or with our collaborators, represent a new approach to the manufacturing and type of therapeutic biologics, the FDA and its foreign counterparts have not yet established any definitive policies, practices or guidelines in relation to these product candidates. Moreover, the FDA may respond to any BLA that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of our product candidates. In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs and therapeutic biologics, and FDA standards, especially regarding product safety, appear to have become more stringent. Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions. In addition, the FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe- use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third- party payors. We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third- party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U. S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects. Delays in obtaining regulatory approval of our manufacturing process may delay or disrupt our commercialization efforts. To date, no product using a cell- free manufacturing process in the United States has received approval from the FDA. Before we can begin to commercially manufacture our product candidates in third- party or our own facilities, we must obtain regulatory approval from the FDA for a BLA that describes in detail the chemistry, manufacturing, and controls for the product. A manufacturing authorization must also be obtained from the appropriate EU regulatory authorities. The timeframe required to obtain such approval or authorization is uncertain. In addition, we must pass a pre- approval inspection of our manufacturing

facility by the FDA before any of our product candidates can obtain marketing approval, if ever. In order to obtain approval, we will need to ensure that all of our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any products that we may develop. Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products. Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post- market authority, including the authority to require labeling changes based on new safety information and to require post- market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third- party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. If we rely on third- party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution. Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls; • fines, warning or untitled letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners; • suspension or revocation of product license approvals; • product seizure or detention or refusal to permit the import or export of products; and • injunctions or the imposition of civil or criminal penalties. The FDA policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business. We also 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. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. 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 drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. ~~For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.~~ The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions, and could greatly impact healthcare and the pharmaceutical industry. ~~Separately, in response to the COVID- 19 pandemic, for a period of time, the FDA temporarily postponed most inspections of foreign manufacturing facilities along with routine surveillance inspections of domestic manufacturing facilities. The FDA has since developed a rating system to determine what categories of regulatory activity can take place in a given geographic region. As of May 2021, the FDA is either continuing, on a case- by- case basis, to conduct " mission- critical " inspections (foreign and domestic) or, where possible to do so safely, resuming prioritized domestic inspections, which generally include preapproval,~~

~~pre- license, surveillance, and for- cause inspections. In February 2022, the FDA stated that limited staff resources and increased workload associated with COVID- 19 impacted its ability to meet user fee performance goals. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic.~~ If a prolonged government shutdown occurs, or if global health concerns ~~continue to~~ 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 may face difficulties from healthcare legislative reform measures. Existing regulatory policies may change and additional government regulations may be enacted that could ~~prevent, limit~~ **affect pricing and third- party payments** ~~or~~ **for** ~~delay regulatory approval of~~ our product candidates **, which could negatively affect our business, financial condition and prospects** . We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or together, the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U. S. pharmaceutical industry. **While** ~~There~~ **there** have been legislative and judicial efforts to modify, repeal or otherwise invalidate all or certain aspects of the ACA ~~, including measures taken during the former presidential administration. By way of example, the Tax Cuts and Jobs Act,~~ or ~~the TCJA~~ **its implementing regulations** , ~~was enacted, effective January 1, 2019, and included, among other things, a provision repealing the tax- based shared responsibility payment imposed by~~ the ACA ~~on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " On June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Thus, the ACA will remain~~ **remains** in effect in its current form. It is ~~possible that~~ **unclear how any such efforts in the future will impact** the ACA ~~will be subject to judicial or Congressional challenges in the future. The 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA- mandated " Cadillac " tax on certain high- cost employer- sponsored insurance plans and the medical device excise tax on non- exempt medical devices, and effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 % to 70 % the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole. " In addition, CMS published a final rule that would give states greater marketplaces, which may have the effect of relaxing essential health benefits required under the ACA for~~ **or our business** ~~plans sold through such marketplaces~~ . In addition, other legislative changes have been proposed and adopted in the United States **federal and state levels** ~~since the ACA was enacted~~ to reduce healthcare expenditures ~~. U. S. federal government agencies also currently face potentially significant spending reductions~~ , **including** ~~which may further impact healthcare expenditures. On August 2, 2011,~~ the Budget Control Act ~~of 2011 among other things~~ , ~~created measures for spending~~ **which, subject to certain temporary suspension periods, imposed 2 %** reductions **in** ~~by Congress. A joint select committee on deficit reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. This includes aggregate reductions of~~ Medicare payments to providers ~~of 2 %~~ per fiscal year **starting** ~~. These reductions went into effect on~~ April 1, 2013 and, due to subsequent legislative amendments to the statute **, that** will remain in effect through ~~2032~~ **2031** , unless additional Congressional action is taken ~~the U.S.Department of Health and Human Services,or HHS,finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan~~ sponsors under Part D,either directly or through pharmacy benefit managers,unless the price reduction is required by law.The rule also creates a new safe harbor for price reductions reflected at the point- of- sale,as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers.The **rule also created a new safe harbor for price reductions reflected at the point- of- sale,as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers.The** implementation of this final rule was delayed by the **Biden administration** ~~Inflation Reduction Act,or IRA,~~ until ~~January 1,~~ . Moreover, on January 2, 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. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop. Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. ~~For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician- administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a~~

~~similar reduction in payments from private payors. In addition,~~ CMS has begun bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and, beginning in 2018, CMS will pay for clinical laboratory services based on a weighted average of reported prices that private payors, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services. Further, on March 16, 2018, CMS finalized its National Coverage Determination, or NCD, for certain diagnostic laboratory tests using next generation sequencing that are approved by the FDA as a companion in vitro diagnostic and used in a cancer with an FDA- approved companion diagnostic indication. Under the NCD, diagnostic tests that gain FDA approval or clearance as an in vitro companion diagnostic will automatically receive full coverage and be available for patients with recurrent, metastatic relapsed, refractory or stages III and IV cancer. Additionally, the NCD extended coverage to repeat testing when the patient has a new primary diagnosis of cancer. ~~Recently there~~ **There** has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The FDA released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada ~~. Further~~ , **and the FDA authorized the first such** ~~in November 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to~~ plan **in** sponsors under Part D, either directly..... was delayed by the Biden administration until January ~~1, 2023 and subsequently delayed by the Inflation Reduction Act, or IRA, until January 1, 2032. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer- sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value- based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1,~~ 2024 ~~, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated~~ . **Recently** ~~Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products. It is unclear to what extent these new requirements will be implemented and to what extent these regulations or any future legislation or regulations by the Biden administration will have on our business~~ , **several healthcare reform** ~~including our ability to generate revenue and achieve profitability. On September 9, 2021, the Biden Administration published a wide- ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. These~~ initiatives ~~recently~~ culminated in the enactment of the IRA in August 2022, which ~~will~~ **allows** , among other things, ~~allow~~ HHS to negotiate the selling price of ~~certain~~ **a statutorily specified number of** drugs and biologics **each year** that CMS reimburses under Medicare Part B and Part D **.** ~~, although this will only~~ **Only** ~~apply to~~ high- expenditure single- source biologics that have been approved for at least 11 years (7 years for **single- source** drugs) ~~. The~~ **can qualify for negotiations, with the** negotiated ~~prices, which will first become effective in 2026, will be capped at a statutory ceiling~~ price **taking effect two years after the selection year** . **Negotiations** ~~Beginning in October 2022~~ for Medicare Part D ~~and January~~ **products begin in** ~~2023~~ **2024 with the negotiated price taking effect in 2026, and negotiations** for Medicare Part B ~~,~~ **products begin in 2026 with** the **negotiated price taking effect in 2028. HHS will announce the negotiated maximum fair price by September 1, 2024, and this price cap, which cannot exceed a statutory ceiling price, will come into effect on January 1, 2026. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA' s price negotiations requirements, but loses that exclusion if it has designations for more than one rare disease or condition, or if it is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations, and by October 1, 2023, each manufacturer of the selected drugs signed a manufacturer agreement to participate in the negotiations. The** IRA also penalizes drug manufacturers that increase prices of Medicare Part D and Part B drugs at a rate greater than the rate of inflation. In addition, the law eliminates the " donut hole " under Medicare Part D beginning in 2025 by significantly lowering the enrollee maximum out- of- pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10 % of Part D enrollees' prescription costs for brand drugs below the out- of- pocket maximum, and 20 % once the out- of- pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties **, some significant** , including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions ~~will take~~ **are taking** effect progressively starting in 2023, although they may be subject to legal challenges. **For example, the provisions related to the negotiation of selling prices of high- expenditure single- source drugs and biologics have been challenged in multiple lawsuits. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and our product candidates.** At the state level, legislatures are increasingly ~~passing legislation~~ **enacting laws** and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law. We may

choose to seek an expanded access program for our product candidates, or to utilize comparable rules in other countries that allow the use of a drug, on a named patient basis or under a compassionate use program. We expect that the ACA, the IRA and other **state or federal** healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Our operations and relationships with healthcare providers, healthcare organizations, customers and third- party payors will be subject to applicable anti- bribery, anti- kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Our current and future arrangements with healthcare providers, healthcare organizations, third- party payors and customers expose us to broadly applicable anti- bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates. In addition, we may be subject to patient data privacy and security regulation by the U. S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti- bribery and healthcare laws and regulations, include the following: • the federal Anti- Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state 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 federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be imposed through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment 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 federal government. In addition, certain marketing practices, including off- label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act; • HIPAA, which imposes criminal and civil liability, prohibits, 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 federal Anti- Kickback Statute, 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; • HIPAA, as amended by HITECH, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information; • the federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advanced practice nurses, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website; • 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; • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; and • certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others: • exclusion from participation in government- funded healthcare programs; • exclusion of company products from coverage under federal health care programs; and • exclusion from eligibility for the award of government contracts for our products. Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could 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 such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management' s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. Our failure to comply with privacy and data security laws, regulations and standards may cause our business to be materially adversely affected. We maintain a quantity of sensitive information, including confidential business and patient health information in connection with our clinical trials **that** ~~, and~~ are subject to US and international laws and regulations governing the privacy and ~~security~~ **data protection** of such information. Each of these laws is subject to varying interpretations and ~~constantly~~ **subject to** evolving ~~. In the United States, there are numerous federal and state privacy and data security laws and~~ regulations ~~governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws~~ . ~~In contrast~~ **For example** , the EU and United Kingdom (" UK ") GDPR, which applies extraterritorially, imposes several strict requirements for controllers and processors of personal information ~~. These~~ **, which** include higher standards for obtaining consent from individuals to process their personal information, increased requirements pertaining to the processing of special categories of personal information (such as health information) and pseudonymized (i. e., key- coded) data, and heightened transfer requirements of personal information from the European Economic Area / UK / Switzerland to countries not deemed to have adequate data protections laws ~~(c~~. **Notably** ~~g.~~, the U. S. is one such country as of January 1, **2024, although effective July 10,** 2023, ~~although active treaty negotiations between~~ the **new EU-** U. S. ~~and the~~ **Data Privacy Framework (" DPF ") has been recognized as adequate under** EU ~~may change that status in 2023~~ **law to allow transfers of personal data from the EU (as well as the U. K. and Switzerland**) **to certified companies in the U. S. However, the DPF is likely to face legal challenge at the Court of Justice of the European Union which could cause the legal requirements for personal data transfers from the Europe to the U. S. to become uncertain once again. We will monitor these legal developments and continue to use best practices to follow established European legal standards to conduct cross- border transfer of personal data** . The GDPR also provides that countries in the European Economic Area may establish their own laws and regulations further restricting the processing of certain personal information, including genetic data, biometric data, and health data. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million (approximately $ 22. 6 million) or 4 percent of the annual global revenues of the noncompliant company, whichever is greater. In the United States, in addition to HIPAA, various federal (for example, the Federal Trade Commission) and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security **that** ~~. Certain state laws~~ may **conflict or** be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than **existing** federal, international, or other state laws ~~, and such laws may differ from each other, all of which may complicate compliance efforts~~ . For example, California, which continues to be a critical state with respect to evolving consumer privacy laws after enacting the California Consumer Privacy Act (the " CCPA "), ~~later~~ **as** amended by ~~ballot measure through~~ the California Privacy Rights Act **,** ~~(the " CPRA "). The CPRA~~ took effect in January 2023 and **may be** ~~enforcement will begin on July 1, 2023,~~ subject to **additional** regulations promulgated through a newly created enforcement agency called the California Privacy Protection Agency (" CPPA "). Failure to comply with the CCPA ~~and the CPRA~~ may result in significant civil penalties, injunctive relief, or statutory or actual damages as determined by the CPPA and California Attorney General ~~through its investigative~~ **, the latter still retaining some CCPA enforcement** authority. ~~Notably~~ **Following California' s lead** , ~~comparable consumer~~ **several other state enacted** privacy laws **that took** ~~are set to take~~ effect in 2023 ~~in~~ **:** ~~other~~ -- **the** ~~states including~~ **Colorado Privacy Act, the Connecticut Personal Data Privacy and Online Monitoring Act, the Utah Consumer Privacy Act, and** the Virginia Consumer Data Protection Act **. Additional state privacy laws are to take effect in 2024: the Florida Digital Bill of Rights** (**July** ~~effective January~~ 1, ~~2023~~ **2024**), **Montana' s Consumer** ~~the Colorado Privacy Act and the Connecticut~~ Data Privacy Act (~~both effective~~ **October 1, 2024), Oregon' s protections for the personal data of consumers enacted through SB 619 (** July 1, ~~2023~~ **2024**), and the ~~Utah Consumer~~ **Texas Data** Privacy **and Security** Act (**July 1** ~~effective December 31~~, ~~2023~~ **2024**) ~~. Compliance with this new privacy legislation may result in additional costs and expense of resources to maintain compliance. There is also discussion in the U. S. of a new comprehensive federal data privacy law to which we would become subject if it is enacted~~ . We cannot provide assurance that (i) current or future legislation will not prevent us from generating or maintaining personal information, or (ii) that patients will consent to the use of their personal information (as necessary). Either of these circumstances may prevent us from undertaking or publishing essential research and development, manufacturing, and commercialization, which could have a material adverse effect on our business, results of operations, financial condition, and prospects. ~~Federal~~ **Further** , ~~state~~ **on July 26** , ~~and foreign government requirements include obligations of~~ **2023, the SEC adopted new cybersecurity disclosure rules for public** companies **that require** ~~to notify regulators and / or individuals of security breaches or other similar reportable incidents experienced by us, or our vendors, contractors, or organizations with whom we had specific contractual obligations to protect our data. Further, the improper access to, use of, or~~ disclosure ~~of our data~~ **regarding cybersecurity risk management (including** ~~or~~ **our board** ~~a third- party~~ ' s ~~personal information could subject us to individual~~ **role in overseeing cybersecurity risks, management' s role**

and expertise in assessing and managing cybersecurity risks and processes ~~or~~ **for assessing, identifying** ~~consumer class action litigation~~ and ~~governmental investigations and proceedings~~ **managing cybersecurity risks) in annual reports on Form 10- K. These new cybersecurity disclosure rules also require the disclosure of material cybersecurity incidents** by **Form 8** ~~federal, state, and local regulatory entities in the United States and by international regulatory entities. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time~~ **K** ~~intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight~~. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self- regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. It is possible that if our practices are not consistent or viewed as not consistent with legal and regulatory requirements ~~, including changes in laws, regulations~~ and ~~standards or new~~ interpretations ~~or applications of existing laws, regulations and standards~~, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, or severe criminal or civil sanctions, all of which may have a material adverse effect on our business, operating results, reputation, and financial condition. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any failure or perceived failure by us to comply with any applicable federal, state, or similar foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties, or judgments. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition, ~~and prospects. Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, which would harm our business. The regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval. Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost- effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third- party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely. There may be significant delays in obtaining reimbursement for newly approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs or therapeutic biologics, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval processes apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for new drugs or therapeutic biologics that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations~~ and prospects. If in the future we are unable to establish U. S. or global sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if they are approved and we may not be able to generate any revenue. We currently have a limited team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. To commercialize any product candidates after approval, we must build, on a territory- by-territory basis, 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 our product candidates receive regulatory approval, we may decide to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. For example, some state and local jurisdictions have licensing and continuing education requirements for pharmaceutical sales representatives, which requires time and financial resources. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory- by- territory basis, 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 our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses. Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the ~~approval~~ **licensure** of biosimilar biological products (both highly similar and interchangeable biological products) was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing reference product. The BPCIA provides a period of exclusivity for products granted " reference product exclusivity, " under which an application for a biosimilar product referencing such products cannot be ~~approved~~ **licensed** by the FDA until 12 years after the first licensure date of the reference product licensed under a BLA. ~~On March 6~~ **During this 12- year period of exclusivity** , ~~2015,~~ **another company may still market a competing version of the reference product if** the FDA ~~approved~~ **licenses a full BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of** ~~the~~ **their** ~~first biosimilar~~ product ~~under~~ **. The law is complex and is still being interpreted and implemented by** the **FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement** BPCIA ~~. FDA has accelerated licensure of biosimilar products since the first biosimilar was approved in 2015. However, FDA has yet to deem a biosimilar product interchangeable with the reference product. While FDA has implemented certain procedures intended to implement the BPCIA, other processes remain in development and~~ may be **fully** adopted by the FDA ~~;~~ **,** any such processes could have **an** ~~a material~~ adverse effect on the future commercial prospects for our ~~biological products~~ **product candidates** ~~. A biological product submitted for licensure under a BLA is eligible for a period of exclusivity that commences on the date of its licensure, unless its date of licensure is not considered a date of first licensure because it falls within an exclusion under the BPCIA~~ . There is a risk **that any product candidates we may develop that are licensed as a biological product under a BLA would not qualify for the 12- year period of exclusivity or** that this exclusivity could be shortened due to congressional action or otherwise, **or that the FDA will not consider any product candidates we may develop to be reference products for competing products,** potentially creating the opportunity for ~~biosimilar~~ **generic** competition sooner than anticipated ~~. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway~~ . Most states have enacted substitution laws that permit substitution of ~~only~~ interchangeable biosimilars. The extent to which a highly similar biosimilar, once ~~approved~~ **licensed** , will be substituted for any one of our reference products that may be approved in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product candidates, our ability to market and derive revenue from the product candidates could be compromised. Undesirable side effects caused by our product candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in more restrictive labeling or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Given the nature of ADCs, it is likely that there may be side effects associated with their use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trials or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. In the event that any of our product candidates receive regulatory approval and we or others identify undesirable side effects caused by one of our products, any of the following adverse events could occur: • regulatory authorities may withdraw their approval of the product or seize the product; • we may be required to recall the product or change the way the 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; • we may be subject to fines, injunctions or the imposition of civil or criminal penalties; • regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication; • we may be required to 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 these occurrences could have a material and adverse effect on our business, financial condition,

results of operations and prospects. While we have been granted a Fast Track Designation by the FDA for luvelta, it may not lead to a faster development or regulatory review or approval process. We have been granted a Fast Track Designation for luvelta for the treatment of patients with platinum- resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior lines of systemic therapy. As part of our business strategy, we may also seek Fast Track Designation for other of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, as we have for luvelta, 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, which may happen in connection with luvelta or other of our product candidates if granted Fast Track Designation. While we have been granted Orphan Drug Designation by the FDA for **luvelta** ~~STRO- 001 for the treatment of multiple myeloma and for STRO-002~~ for the treatment of Pediatric (CBF / GLIS) AML, if we decide to seek Orphan Drug Designation for some of our other product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for orphan drug exclusivity. We have been granted Orphan Drug Designation by the FDA for ~~STRO- 001 for the treatment of multiple myeloma and for~~ luvelta for the treatment of Pediatric CBF / GLIS AML ~~and our collaborator BMS was granted Orphan Drug Designation by the FDA for CC- 99712~~. As part of our business strategy, we may seek Orphan Drug Designation for our other product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and therapeutic biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or therapeutic biologic as an orphan drug if it is a drug or therapeutic biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals 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 or therapeutic biologic will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as tax advantages and user fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same ~~indication~~ **condition** for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. Even if we obtain Orphan Drug Designation for our product candidates in specific ~~indications~~ -- **conditions**, we may not be the first to obtain marketing approval of these product candidates for the orphan- designated ~~indication~~ **condition** due to the uncertainties associated with developing pharmaceutical products **; in such case, no orphan drug exclusivity would be available unless we could demonstrate " clinical superiority** . **"** In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan- designated ~~indication~~ **condition** or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs or therapeutic biologics with different principal molecular structural features can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug or therapeutic biologic with the same principal molecular structural features for the same condition if the FDA concludes that the later drug or therapeutic biologic 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 therapeutic biologic nor gives the drug or therapeutic biologic any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for our product candidates, we may never receive such designations. The tax reform legislation signed into law on December 22, 2017 reduced the amount of the qualified clinical research costs for a designated orphan product that a sponsor may claim as a credit from 50 % to 25 %. This may further limit the advantage and may impact our future business strategy of seeking the Orphan Drug Designation. If we decide to pursue accelerated approval for any of our product candidates, it 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. In the future, we may decide to pursue accelerated approval for one or more of our product candidates. Under the FDA' s accelerated approval program, the FDA may approve a drug or biologic for a serious or life- threatening disease or condition that provides a meaningful advantage over available therapies based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. For drugs or biologics granted accelerated approval, post- marketing confirmatory trials are required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence, and the FDA may require that the trial be designed, initiated, and / or fully enrolled prior to approval. If we were to pursue accelerated approval for a product candidate for a disease or condition, we would do so on the basis that there is no available therapy for that disease or condition or that our product candidate provides a benefit over available therapy. If standard of care were to evolve or if any of our competitors were to receive full approval on the basis of a confirmatory trial for a drug or biologic for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, the disease or condition would no longer qualify as one for which there is no available therapy, and accelerated approval of our product candidate would not occur without a showing of benefit over available therapy. Many cancer therapies rely on

accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials. ~~We have initiated discussions with the FDA regarding an appropriate trial design for a registration- directed trial of luvelta to potentially support an accelerated approval; however, whether~~ **Whether** any trial is sufficient to receive FDA approval under the accelerated approval pathway will depend on the **design and** safety and efficacy results of such trial and will only be determined by the FDA upon review of **the trial design and** a submitted BLA. Moreover, the FDA may withdraw approval of any product candidate approved under the accelerated approval pathway if, for example: • the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with such product; • other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use; • we fail to conduct any required post- approval trial of our product candidate with due diligence; or **•** we disseminate false or misleading promotional materials relating to the relevant product candidate. In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs. Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called " dangling " or delinquent accelerated approvals, where confirmatory studies have not been completed or where results did not confirm benefit, but for which marketing approval continues in effect, and some companies have subsequently voluntarily requested withdrawal of approval of their products. In addition, the Oncology Center of Excellence has ~~recently~~ announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post- marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies. **Further** ~~In addition~~ , the ~~recent~~ enactment of The Food and Drug Omnibus Reform Act, or FDORA, included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post- approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post- approval study and requires sponsors to submit progress reports for required post- approval studies and any conditions required by the FDA. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post- approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports. Risks Related to Our Common Stock Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. We expect our operating results to be subject to quarterly and annual fluctuations. Our net income or loss and other operating results will be affected by numerous factors, including: • variations in the level of expense related to the ongoing development of our XpressCF ® and XpressCF ® platforms, our product candidates or future development programs; • the fair value of our holding of common stock of Vaxcyte; • results of preclinical and clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners; • our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements; • any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved; • additions and departures of key personnel; • strategic decisions by us or our competitors, such as acquisitions, divestitures, spin- offs, joint ventures, strategic investments or changes in business strategy; • if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates; • regulatory developments affecting our product candidates or those of our competitors; • **the impact of accounting principles and tax laws, including as a result of recent tax law changes; •** epidemics, pandemics or contagious diseases ~~, such as COVID- 19~~ ; ~~and~~ • changes in general market and economic conditions ~~.~~ **; and • cybersecurity incidents** If our quarterly and annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly and annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly and annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions: • establish a classified board of directors so that not all members of our board are elected at one time; • permit only the board of directors to establish the number of directors and fill vacancies on the board; • provide that directors may only be removed " for cause " and only with the approval of two- thirds of our stockholders; • require super- majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws; • authorize the issuance of " blank check " preferred stock that our board could use to implement a stockholder rights plan; • eliminate the ability of our stockholders to call special meetings of stockholders; • prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders; • prohibit cumulative voting; and • establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings. In addition, our restated certificate of incorporation, to the fullest extent permitted by law, provides that 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, or the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Furthermore, our amended and restated bylaws also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act (a Federal Forum Provision). While the Supreme Court of the State of Delaware has held that such provisions are facially valid under Delaware law, there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case; application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the specified courts could face additional litigation costs in pursuing any such claim. The specified courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find these provisions of our governance documents inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, Section 203 of the DGCL may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15 % or more of our common stock. **The exclusive forum provision in our organizational documents may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers or other employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims. Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, 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 DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision. This 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 any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.** Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. The market price of our stock may be volatile, and you could lose all or part of your investment. The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the purchase price. The market price for our common stock may be influenced by many factors, including the other risks described in this section and the following: • results of preclinical studies and clinical trials of our product candidates, or those of our competitors or our existing or future collaborators; • regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates; • the success of competitive products or technologies; • introductions and

announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements; • actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms; • actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us; • the success of our efforts to acquire or in- license additional technologies, products or product candidates; • developments concerning current or future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners; • market conditions in the pharmaceutical and biotechnology sectors; • general economic uncertainty and capital markets disruptions, including ~~rising~~ **changes in** interest rates ~~and~~ **, rising** inflation **, potential instability with respect to the federal debt ceiling and budget and potential government shutdowns related thereto** , which have been substantially impacted by **regional** geopolitical instability due to the **impact of geopolitical tensions and the** ongoing military ~~conflict~~ **conflicts** ~~in Ukraine~~ **around the world** ; • any adverse impact of **health** ~~the COVID- 19 pandemic~~ **pandemics** , including on our clinical trials and clinical trial operations; • announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments; • developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products; • our ability or inability to raise additional capital and the terms on which we raise it; • the recruitment or departure of key personnel; • changes in the structure of healthcare payment systems; • actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally; • our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • announcement and expectation of additional financing efforts; • speculation in the press or investment community; • trading volume of our common stock; • sales of our common stock by us or our stockholders; • ~~the concentrated ownership of our common stock; •~~ changes in accounting principles **or tax laws** ; • terrorist acts, acts of war or periods of widespread civil unrest, including the ongoing armed ~~conflict~~ **conflicts** ~~in Ukraine~~ **around the world** ; • natural disasters, epidemics, pandemics or contagious diseases, and other calamities; • **political instability** ~~a temporary federal government shutdown~~ ; and • general economic, industry and market conditions. In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and adverse impact on the market price of our common stock. The future sale and issuance of equity or of debt securities that are convertible into equity will dilute our share capital. We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of 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 equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock. A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. 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, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock. For example, ~~in April 2021,~~ we ~~entered into the~~ **are party to a** Sales Agreement with Jefferies, pursuant to which, from time to time, we may offer and sell through Jefferies ~~up to $ 100. 0 million of our~~ common stock pursuant to one or more " at the market " offerings. Sales of our common stock under the Sales Agreement with Jefferies could be subject to business, economic or competitive uncertainties and contingencies, many of which may be beyond our control, and which could cause actual results from the sale of our common stock to differ materially from expectations. Any future sales of common stock through our " at the market " offering program will result in dilution and may have a negative impact on the price of our common stock. We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. General Risk Factors Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our business, financial condition or results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets, and ~~, in recent months,~~ the global economy has ~~been~~ **continued to be** impacted by ~~increasing~~ **changes in** interest rates ~~and~~ **, rising** inflation **, potential uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto** . Likewise, the capital and credit markets may be adversely affected by **rising regional geopolitical tensions** ~~the recent conflict between Russia and Ukraine, and the possibility of a wider European or global conflict~~ , and global sanctions imposed in response thereto. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply

disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. 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 will be 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 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, financial condition and results of operations, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such 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 a decline in our stock price or trading volume. The requirements of being a public company may strain our resources, divert management' s attention and affect our ability to attract and retain additional executive management and qualified board members. The additional requirements we must comply with may strain our resources and divert management' s attention from other business concerns. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of The Nasdaq Global Select Market, and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time- consuming, or costly, and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting **. Additionally, we may be subject to stockholder activism, which can be costly and time- consuming, disrupting our operations and diverting the attention of management and may lead to additional compliance costs and impact the manner in which we operate our business** . In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management' s attention may be diverted from other business concerns, which could adversely affect our business and operating results. In order to comply with these requirements, we may need to hire more employees in the future or engage outside consultants, or may have difficulty attracting and retaining sufficient employees, which would increase our costs and expenses. As a result of no longer being an emerging growth company, we have incurred, and will continue to incur, significant additional expenses that we did not previously incur in complying with the Sarbanes- Oxley Act and rules implemented by the SEC. The cost of compliance with Section 404 of the Sarbanes- Oxley Act has required us to incur substantial accounting expense and expend significant management time on compliance- related issues as we implement additional corporate governance practices and comply with reporting requirements. We became a " smaller reporting company " as of December 31, 2022 ~~, meaning that the market value of our stock held by non- affiliates was less than $ 560. 0 million and our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year~~ . We will continue to be a smaller reporting company if either (i) the market value of our stock held by non- affiliates is less than $ 250. 0 million or (ii) our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than $ 700. 0 million. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10 ~~-~~ - K and are eligible to take advantage of certain of the reduced disclosure obligations regarding compensation disclosures in 2023. As a smaller reporting company and a " non- accelerated filer ", we still need to comply with Section 404 (a) of the Sarbanes- Oxley Act, which will continue to require substantial management time and expense. In addition, changing laws, regulations, and standards relating to corporate governance, stockholder litigation, and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, making some activities more time consuming, and increasing the likelihood and expense of litigation. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve or otherwise change over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters, higher costs necessitated by ongoing revisions to disclosure and governance practices, and increased expenses and management attention due to actual or threatened litigation. We intend to invest resources to comply with evolving laws, regulations and standards (or changing interpretations of them), and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If our efforts to comply with these laws, regulations, and standards differ from the activities intended by regulatory or governing bodies, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected. Being a public company and complying with the associated rules and regulations, and being subject to heightened likelihood of litigation, makes it more expensive for us to obtain director and officer liability insurance, the costs of which can fluctuate significantly from year- to- year due to general market conditions in obtaining such insurance, but in recent years have risen significantly, consistent with the increase in market rates. As a result, we may be required to accept reduced coverage, incur substantially higher costs to obtain coverage or may be unable to obtain coverage on economically reasonable terms, or at all. These factors could also make it more difficult for us to attract and retain qualified executives and qualified members of our board of directors, particularly to serve on our audit committee, our compensation committee, and our nominating and corporate governance committee. As a result of disclosure of information in filings required of a public company, our business and financial condition has become more visible, which may result in threatened or actual litigation, including by competitors. If such claims are successful, our business and operating results could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the

resources of our management and adversely affect our business and operating results. In addition, as a result of our disclosure obligations as a public company, we could face pressure to focus on short- term results, which may adversely affect our ability to achieve long- term profitability. We may be subject to securities litigation, which is expensive and could divert management attention. The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. ~~101~~