**Risk Factors Comparison 2024-03-07 to 2023-03-30 Form: 10-K**

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes and the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, growth prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report, and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part. Risk Factor Summary Our business operations are subject to numerous risks and uncertainties, including those outside of our control, that could cause our actual results to be harmed, including risks regarding the following: ▪ We are early in our development efforts and all of our product candidates are in preclinical development or early stage clinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and commercialize one or more of our product candidates, our business will be materially adversely affected and we may never generate any product revenue. ▪ The use of engineered IgM antibodies is a novel and unproven therapeutic approach **,** and our development of our product candidates ~~,~~ and our discovery programs may never lead to a marketable product. ▪ Clinical trials are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety and efficacy of our product candidates. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities or provide the basis for regulatory approval. ▪ If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to seek or obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue. ▪ If we experience delays or difficulties in the enrollment of patients in clinical trials, including **because** ~~as a result~~ of competition for patients, we will be unable to complete these trials on a timely basis, if at all. ▪ Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include new safety warnings, contraindications or precautions, or otherwise limit their sales. No regulatory agency has made a determination that any of our product candidates are safe or effective for use by the general public for any indication. ▪ We face significant competition from entities that have developed or may develop product candidates for the treatment of diseases that we are initially targeting, including companies developing novel treatments and technology platforms. If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted. ▪ The manufacturing of our product candidates is complex. We and our third- party manufacturers have encountered and may continue to encounter difficulties in the production of our product candidates, and supply chain shortages have limited and may continue to limit our access to raw materials and other supplies. If we continue to encounter any such difficulties, our ability to manufacture drug substances or supply our product candidates for preclinical studies or clinical trials or, if approved, for commercial sale, could be further delayed or halted entirely. ▪ We may not be successful in our efforts to use and expand our IgM platform to build a pipeline of product candidates. ▪ We face risks related to health epidemics and other outbreaks, such as COVID- 19, which could significantly disrupt our business operations or otherwise result in material adverse impact to us. ▪ ~~Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. Index to Financial Statements ▪~~ We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability **. ▪ Drug development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives. Index to Financial Statements ▪ We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development programs or operations. ▪ Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. ▪ Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation** . ▪ Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Risks Related to Our Business and the Development and Commercialization of Our Product Candidates We are early in our development efforts and have not yet completed the development of any of our product candidates. As a result, we are not currently permitted to market or sell any of our product candidates in any country, and we may never be able to do so in the future. We have a limited number of product candidates and discovery programs, all of which are in preclinical development or early stage clinical development and we have not received marketing approval for any of our product candidates. Our product candidates will require clinical development, evaluation of preclinical, clinical and manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we generate any revenues from product sales, if ever. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals. Our ability to generate product revenue and achieve and sustain profitability depends on, among other things, obtaining regulatory approvals for our product candidates. Obtaining regulatory approval of our product candidates will depend on many factors, including, but not limited to, the following: ▪ completing process development, manufacturing and formulation activities; ▪ initiating, enrolling patients in and completing clinical trials of product candidates on a timely basis; ▪ developing and maintaining adequate manufacturing capabilities either by ourselves or in connection with third- party manufacturers; and ▪ demonstrating with substantial evidence the efficacy, safety and tolerability of product candidates to the satisfaction of the FDA or any comparable foreign regulatory authority for marketing approval. Many of these factors are wholly or partially beyond our control, including clinical advancement, the regulatory submission process and changes in the competitive landscape. If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to develop product candidates at all, and our business will be materially adversely affected. The use of engineered IgM antibodies is a novel and unproven therapeutic approach and our development of our product candidates and our discovery programs may never lead to a marketable product. Our product candidates are based on engineered IgM antibody approaches that differ from current antibody therapies and are unproven. Our IgM antibodies ultimately may not be as safe or effective as IgG antibodies that have been approved or may in the future be approved by the FDA. Further, we are not aware of any therapeutic IgM antibodies that have been approved by the FDA. The scientific evidence to support the feasibility of developing our product candidates and discovery programs is both preliminary and limited. We may ultimately discover that our product candidates and discovery programs do not possess some of the properties that are necessary for therapeutic efficacy, and we may also discover that they do not possess those characteristics that we believe may be helpful for therapeutic effectiveness, including stronger binding that increases efficacy. Our IgM antibodies may also have significant undesirable characteristics, such as immunogenicity, which would limit their ability to be developed as effective and safe therapeutics. In addition, we may discover that our IgM antibodies are not as safe as IgG antibodies. We may not succeed in demonstrating safety and efficacy of these product candidates or discovery programs in clinical trials, notwithstanding results in preclinical studies. As a result, we may never succeed in developing a marketable product. We may discover that the half- life, tissue distribution or other pharmacodynamic or pharmacokinetic characteristics of our IgM antibodies render them unsuitable for the therapeutic applications we have chosen or ~~are not~~ **otherwise non-** competitive with IgG antibodies. We may also experience manufacturing, formulation or stability problems with one or more of our IgM antibodies which may render them unsuitable for use as therapeutic drug products. The FDA has limited experience with IgM antibody- based therapeutics, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. For example, the FDA may require us to provide additional data to support our regulatory applications. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be subject to post- marketing testing requirements to maintain regulatory approval. In addition, upon obtaining any marketing approvals, we may have difficulty in establishing the necessary sales and marketing capabilities to gain market acceptance. Moreover, advancing our product candidates and our discovery programs as novel products creates other significant challenges for us, including educating medical personnel regarding a novel class of engineered antibody therapeutics and their potential efficacy and safety benefits, as well as the challenges of incorporating our product candidates, if approved, into treatment regimens. If any of our product candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, and it may prove to be difficult or impossible to finance the further development of such pipeline. Any of these events would have a material and adverse effect on our business, financial condition, results of operations and prospects. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical development and then extensive clinical trials to demonstrate their safety and efficacy. Clinical testing is expensive and difficult to design and implement. Clinical testing can take many years to complete, and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. We will be required to demonstrate with substantial evidence through well- controlled clinical trials that our product candidates are safe and effective for use in a diverse patient population before we can seek regulatory approvals for their commercial sale. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional and expansive preclinical or clinical testing. Positive or timely results from preclinical or early- stage trials do not ensure positive or timely results in future clinical trials or registrational clinical trials because product candidates in later- stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities, despite having progressed through preclinical studies or initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials **. In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, any of which could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any regulatory approvals we may have obtained. If the Supreme Court reverses or curtails the Chevron doctrine, which gives deference to regulatory agencies in litigation against the FDA and other agencies, more companies may bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA' s authority, lead to uncertainties in the industry, and disrupt the FDA' s normal operations, which could delay the FDA' s review of our regulatory submissions** . Interim, preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, preliminary or topline data from clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Interim or preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. Adverse differences between interim, preliminary or topline data and final data could significantly harm our reputation and business prospects. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Moreover, preliminary, interim and topline data are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available when patients mature on study, patient enrollment continues or as other ongoing or future clinical trials with a product candidate further develop. Past results of clinical trials may not be predictive of future results. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically more extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. Similarly, even if we **can** ~~are able to~~ complete our planned and ongoing preclinical studies and clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory approval. We have obtained, and where appropriate in the future may seek, approval from the FDA or comparable foreign regulatory authorities through the use of expedited approval pathways, such as Fast Track designation and Breakthrough Therapy designation, orphan drug designation, or accelerated approval. Even if we receive accelerated approval from the FDA or comparable regulatory authorities, if our confirmatory clinical trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA or such other regulatory authorities may seek to withdraw accelerated approval. Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our product candidates from the FDA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA' s implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, additional post- approval confirmatory clinical trials to verify and describe the drug' s clinical benefit. If such post- approval clinical trials fail to confirm the drug' s clinical benefit, the FDA may withdraw its approval of the drug. Further, in December 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act (FDORA), was signed into law. FDORA made several changes to the FDA' s authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post- approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non- compliance with post- approval requirements. **In March 2023, the FDA issued a draft guidance on clinical trial considerations for supporting accelerated approval of oncology therapeutics, noting that although single- arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach for more robust efficacy and safety assessment. To the extent the FDA requires us to amend the design of our clinical trials or requires additional trials to meet changes in the data requirements for approval, our clinical timelines and approval will be delayed, which can have an adverse effect on our business and operations.** Prior to seeking accelerated approval, we may seek feedback from the FDA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a **Biologics License Application (** BLA **)** for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e. g., Fast Track designation, Breakthrough Therapy designation or orphan drug designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further clinical trials prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA' s priority review procedures. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. For example, **because** ~~as a result~~ of supply chain constraints and staffing issues at one of our CMOs, **we had to postpone** the filing date of our IND application for **one of** ~~IGM-7354 was adjusted and we had to make certain other adjustments, and we may have to make further adjustments in the future, with respect to this or~~ **our** ~~other programs~~ **clinical candidates** . We also experienced questions from the FDA on issues related to starting dose and sequencing of healthy volunteers and patients, delivery device and non- drug substance formulation components that delayed our original plans to advance IGM- 6268, a former clinical candidate, into the clinic. The commencement or completion of ~~these~~ **our** clinical trials could be substantially delayed or prevented by many factors, including: ▪ further discussions with the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials; ▪ the limited number of, and competition for, suitable study sites and investigators to conduct our clinical trials, many of which may already be engaged in other clinical trial programs with similar patients, including some that may be for the same indication as our product candidates; ▪ any delay or failure to obtain timely approval or agreement to commence a clinical trial in any of the countries where enrollment is planned; ▪ inability to obtain sufficient funds required for a clinical trial; ▪ clinical holds on, or other regulatory objections to, a new or ongoing clinical trial; ▪ delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials; ▪ delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs; ▪ delay or failure to obtain institutional review board (IRB) approval to conduct a clinical trial at a prospective site; ▪ the FDA or other comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial; ▪ slower than expected rates of patient recruitment and enrollment; ▪ failure of patients to complete the clinical trial; ▪ the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects; ▪ unforeseen safety issues, including severe or unexpected drug- related adverse effects experienced by patients, including possible deaths; ▪ lack of efficacy during clinical trials; ▪ termination of our clinical trials by one or more clinical trial sites; ▪ inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols; ▪ inability to monitor patients adequately during or after treatment by us or our CROs; ▪ our CROs or clinical study sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study; ▪ the inability to produce or obtain sufficient quantities of a product candidate to complete clinical trials; ▪ inability to address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial; ▪ the impact of, and delays related to, health epidemics such as the COVID- 19 pandemic; and ▪ the need to suspend, repeat or terminate clinical trials as a result of non- compliance with regulatory requirements, inconclusive or negative results or unforeseen complications in testing; and the suspension or termination of our clinical trials upon a breach or pursuant to the terms of any agreement with, or for any other reason by, any future strategic partners that have responsibility for the clinical development of any of our product candidates. Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly modify our clinical development plans to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by us, the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us. Any failure or significant delay in commencing or completing clinical trials for our product candidates, any failure to obtain positive results from clinical trials, any safety concerns related to our product candidates, or any requirement to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished. We may ~~not be able to initiate~~ **experience difficulties in patient enrollment in** ~~or~~ **our** ~~continue~~ clinical trials for ~~our product candidates if we are unable to identify~~ **a variety of reasons, including supply chain disruptions, staffing shortages** and **other business and economic disruptions resulting from geopolitical actions, including war and terrorism, natural disasters, including earthquakes, typhoons, floods and fires, as well as other disruptions resulting from the impact of public health factors, including the COVID- 19 pandemic, business disruptions of our strategic partners, third- party manufacturers, suppliers and other third parties upon which we rely. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to** enroll a sufficient number of ~~eligible~~ patients ~~to participate~~ **who remain** in ~~these~~ -- **the** ~~trials~~ - **trial until completion of treatment and adequate follow- up** ~~as required by the FDA or comparable foreign regulatory authorities~~ . ~~Patient~~ **The** enrollment ~~, a significant factor in the timing~~ of **patients depends on** ~~clinical trials, is affected by~~ many factors **,** including **: •**

the size and nature of the patient population ~~,~~ **; •** the severity of the disease under investigation ~~,~~ **; •** the proximity of subjects to clinical sites ~~,~~ **and ability of subjects to travel to clinical trial sites; •** continued enrollment of prospective patients by clinical trial sites ~~,~~ **; •** efforts to facilitate timely enrollment ~~,~~ **; •** the eligibility criteria for the trial ~~,~~ **; •** the design of the clinical trial ~~,~~ **; •** patient referral practices of physicians ~~,~~ **; •** ability to obtain and maintain patient consents ~~,~~ **; •** ability to monitor patients adequately during and after treatment ~~,~~ **; •** risk that enrolled subjects will drop out before completion ~~and~~ **; •** clinicians' and patients' perceptions as to the potential advantages and disadvantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating ~~. Further~~ **; and • inability to enroll, or delay in enrollment of** , patients ~~may not be able to visit clinical trial sites for dosing or data collection purposes~~ due to **outbreaks** ~~limitations on travel~~ and **public health crises, such as** ~~physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit~~ the **COVID- 19** ~~clinical trial sites during the~~ pandemic. In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical trials for the same indications and seek to enroll patients in their studies that may otherwise be eligible for our clinical studies or trials, which could lead to slow recruitment and delays in our clinical programs. Further, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites. Moreover, because our product candidates represent a departure from existing cancer treatments, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, IgG antibody therapy or CAR- T treatment, rather than enroll patients in our clinical trials. Our inability to enroll ~~a~~ sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. If we are unable to enroll a sufficient number of patients that will complete clinical testing, we will be unable to seek or gain marketing approval for such product candidates and our business will be harmed. Even if we **can** ~~are able to~~ enroll a sufficient number of patients in our clinical studies or trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. All of our product candidates and discovery programs are in preclinical development or early stage clinical development, and not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from our product candidates could arise at any time during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. **Of** ~~We announced the dosing of the first patient in~~ our **product candidates** ~~Phase 1 clinical trial of imvotamab, IGM- 8444, and IGM- 7354~~ in ~~October 2019~~ **active development** , **we** ~~September 2020, and January 2023, respectively. We~~ have only disclosed ~~initial~~ **early** safety data in humans from ~~our~~ Phase 1 clinical trials **,** ~~of imvotamab~~ and **our** ~~IGM- 8444. Our~~ preclinical and ~~our~~ discovery programs have not been tested on humans at all. **We** ~~While we~~ are encouraged by the safety profile of imvotamab ~~in our Phase 1 clinical trial for the treatment of relapsed / refractory NHL,~~ and **the** ~~we have observed a~~ relatively low rate of cytokine release syndrome (CRS) **observed** in ~~the patients dosed to date~~ **our previous clinical trial; however** , **we may see cases of** ~~a few patients have experienced more~~ serious CRS **in** ~~. While this observation is preliminary, particularly given the small number of~~ patients ~~, we are taking steps to address possible CRS in certain patients. It is possible that these steps or other steps that we take may not be successful, and we may see additional cases of serious CRS~~ in future ~~patients~~ **clinical trials** , which may delay our clinical testing of imvotamab or delay or prevent marketing approval in the future. In our preclinical studies, we may observe undesirable characteristics of our product candidates. This may prevent us from advancing them into clinical trials, delay these trials or limit the extent of these trials. Despite our preclinical data, toxicity observations in clinical testing, if they occur, may limit our ability to develop our product candidates or may constitute a dose limiting toxicity. The results of ongoing or future clinical trials may also show that our product candidates and / or our discovery programs may cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or comparable foreign regulatory authorities, or result in marketing approval from the FDA or comparable foreign regulatory authorities with restrictive label warnings or for limited patient populations, or result in potential product liability claims. No regulatory agency has made any determination that any of our product candidates or discovery programs is safe or effective for use by the general public for any indication. Even if any of our product candidates receive marketing approval, if we or others later identify undesirable or unacceptable side effects caused by such products: ▪ regulatory authorities may require us to take our approved product off the market; ▪ regulatory authorities may require the addition of labeling statements, specific warnings, contraindication, precaution or field alerts to physicians and pharmacies; ▪ we may be required to change the way the product is administered, limit the patient population who can use the product or conduct additional clinical trials; ▪ we may be subject to limitations on how we may promote the product; ▪ sales of the product may decrease significantly; ▪ we may be subject to litigation or product liability claims; and ▪ our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future products. The development and commercialization of drugs and therapeutic biologics is highly competitive and subject to rapid and significant technological change. We are currently developing biotherapeutics that will compete with other drugs and therapies that currently exist or are being developed in the segments of the pharmaceutical, biotechnology and other related markets that develop oncology treatments. Product candidates we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for the research, development, manufacturing and commercialization of cancer immunotherapies. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA or other regulatory approval or discovering, developing and commercializing products in our field before we do. There are **many** ~~a large number of~~ companies developing or marketing treatments for cancer, including most major pharmaceutical and biotechnology companies, as well as many smaller biotechnology companies. These treatments consist both of small molecule drug products as well as biologics that work by using antibody therapeutic platforms to address specific cancer targets. We face significant competition from pharmaceutical and biotechnology companies that target specific tumor- associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell redirecting therapeutics (e. g., T cell engagers), adoptive cellular therapies (e. g., CAR- T), antibody drug conjugates, targeted radiopharmaceuticals, targeted immunotoxin and targeted cancer vaccines. We are aware of other companies with competing products or product candidates that target the same proteins, including CD20, DR5, **and** CD38 ~~and CD123~~, or that utilize similar mechanisms ~~, including targeted and untargeted IL- 15~~, as our product candidates in clinical or preclinical development. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than the products that we may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biotechnology industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. The manufacturing of our product candidates is complex. We and our third- party manufacturers have encountered and may continue to encounter difficulties in the production of our product candidates, and supply chain shortages have limited and may continue to limit our access to raw materials and other supplies. If we continue to encounter any such difficulties, our ability to manufacture drug substance or supply our product candidates for preclinical studies or clinical trials or, if approved, for commercial sale, could be further delayed or halted entirely. We have spent significant resources to date on developing our current manufacturing processes and know- how to produce sufficient yields and optimize functionality in conjunction with our contract manufacturers. In 2021, we completed construction and began to operate a cGMP manufacturing facility for the manufacture of clinical trial drug materials. We may construct additional manufacturing facilities to produce commercial supply for any approved products. **We** ~~To do so, we~~ will need to scale our manufacturing operations, as we do not currently have the infrastructure or capability internally to manufacture sufficient yields needed to advance all of our product candidates and discovery programs in preclinical studies and clinical trials **and currently rely on our third- party manufacturers for the majority of our product candidate production** . Accordingly, we ~~will~~ **may** be required to make significant further investments to expand our manufacturing facilities in the future, and our efforts to scale our internal manufacturing capabilities may not succeed. Also, historically IgM antibodies have been particularly difficult to manufacture and CMOs have limited experience in the manufacturing of IgM antibodies. The process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics, difficulties in scaling the production process and shipping issues. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. For example, **because** ~~as a result~~ of supply chain constraints and staffing issues at one of our CMOs, we ~~have~~ previously **had to** ~~adjusted~~ -- **adjust** the anticipated filing date of our IND application for **one of** ~~IGM- 7354 and we have had to make certain other adjustments, and we may have to make further adjustments in the future, with respect to this or~~ **our** ~~other programs~~ **clinical candidates** . If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, and we could be subject to sanctions, restrictions on the product candidate or on the manufacturing facilities, product liability claims or other adverse consequences, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations. Any interruption in the supply of clinical drug product from any cause could adversely affect the timing, enrollment and scope of our ongoing clinical trials. All of our engineered antibodies are manufactured by culturing cells from a master cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMP. It is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks, and we may fail to have adequate backup should any particular cell bank be lost in a catastrophic event. Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write- offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Furthermore, it is too early to estimate our cost of goods sold. The actual cost to manufacture our product candidates could be greater than we expect because we are early in our development efforts and the use of engineered IgM antibodies is a novel therapeutic approach. Failure to develop our own manufacturing capacity may hamper our ability to further process improvement, maintain quality control, limit our reliance on contract manufacturers and protect our trade secrets and other intellectual property. A key element of our strategy is to leverage our IgM platform to expand our pipeline of antibody product candidates. Although our research and development efforts to date have resulted in a pipeline of product candidates, we may not be able to develop product candidates that are safe and effective. In addition, although we expect that our IgM platform will allow us to continue to develop a steady stream of product candidates, we may not prove to be successful at doing so. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, be competitive with alternatives, or otherwise achieve market acceptance. If we do not successfully develop and begin to commercialize product candidates, we will not be able to generate any product revenue, which would adversely affect business. We may expend our limited resources to pursue product candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Due to the significant resources required for the development of our programs, we must focus our programs on specific product candidates and indications and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or indications may not lead to the development of any viable commercial product and may divert resources away from better opportunities. For example, **in December 2023,** ~~due to the changing COVID- 19 clinical and regulatory environment~~ we ~~discontinued~~ **committed to the Strategic Refocusing, pursuant to which we suspended** clinical development **activities for certain product candidates** ~~of IGM- 6268 after completing the Phase 1 clinical trial~~ . ~~Similarly,~~ **This decision** ~~our~~ **or** potential **future** decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the oncology or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities **, fail to recoup our research and development and other investments in the clinical programs we have selected** , be required to forego or delay pursuit of opportunities with other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights. We face risks related to health epidemics and other outbreaks, such as COVID- 19, which could significantly disrupt our operations or otherwise result in material adverse impacts to us. Our business could be adversely impacted by the effects of health epidemics and other outbreaks, including: ▪ delays or difficulties in enrolling and retaining patients in our ongoing and planned clinical trials, and incurrence of additional costs as a result of any preclinical study and clinical trial delays and adjustments; ▪ delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; ▪ shutdowns or continued business disruptions experienced by suppliers and other third parties with whom we conduct business; ▪ diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials; ▪ interruption or delays of key clinical trial activities, such as clinical trial site monitoring and collecting sufficient clinical data, patient safety considerations or limitations on travel imposed or recommended by federal or state governments, employers and others; ▪ other limitations on resources that would otherwise be focused on the conduct of our business or our current or planned clinical trials or preclinical research, including because of sickness, the desire to avoid contact with large groups of people or government restrictions; ▪ delays in receiving approval from regulatory authorities to initiate our planned clinical trials; ▪ delays in receiving the supplies, materials and services needed to conduct clinical trials and preclinical research or to support manufacturing activities of our business and that of our suppliers or contractors; ▪ changes in clinical site policies and procedures for conducting clinical trials during the pandemic; ▪ changes in regulations as part of a response to health epidemics or other outbreaks which may require us to change the ways in which our clinical trials are conducted and incur unexpected costs, or require us to discontinue the clinical trials altogether; and ▪ delays in necessary interactions with regulators, ethics committees and other important agencies and contractors. **On May 11, 2023, the federal government ended the COVID- 19 public health emergency, which ended a number of temporary changes made to federally funded programs, although some continue to be in effect.** We are actively monitoring, evaluating **,** and responding to developments relating to COVID- 19, including new strains of the disease ~~that have emerged in certain locations, vaccination status both locally and globally, and changing restrictions on travel and other protocols as set forth by the Centers for Disease Control and Prevention and other government authorities~~ . The extent to which COVID- 19, including any variants that have emerged or may emerge in the future, or any other health epidemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of a particular virus and its variants and the actions to contain it or treat its impact, among others . We cannot at this time quantify...... pursue our growth strategy will be limited . Material changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay. As product candidates are developed through preclinical to late- stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing, planned or future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue. The design or execution of our clinical trials may not support regulatory approval. The design or execution of a clinical trial can determine whether its results will support regulatory approval and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in potential future Phase 3 clinical trials or registration trials. The FDA or comparable foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post- marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates. Failure to successfully obtain regulatory approval could have a material adverse impact on our business and financial performance. Even if any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third- party payors, in which case revenue generated from their sales would be limited. 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 price and otherwise will be accepted in the market. The antibodies we are developing use relatively new technologies. Market participants with significant influence over acceptance of new treatments, such as physicians and third- party payors, may not adopt a product or treatment based on our technologies, and the medical community and third- party payors may not accept and use, or provide favorable reimbursement for, any product candidates developed by us. The commercial success of our product candidates will depend upon their acceptance among physicians, patients, the medical community and third- party payors. The degree of market acceptance of any of our product candidates will depend on a number of factors, including: ▪ the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments; ▪ limitations or warnings contained in the approved labeling for our product candidates; ▪ changes in the standard of care for the targeted indications for our product candidates; ▪ the clinical indications for which any product candidate is approved; ▪ lack of significant adverse side effects; ▪ the effectiveness of sales and marketing efforts; ▪ availability and extent of coverage and adequate reimbursement, as well as pricing, by managed care plans and other third- party payors, including government authorities; ▪ patients' willingness to pay out- of- pocket in the absence of coverage and / or adequate reimbursement from third- party payors; ▪ timing of market introduction of our product candidate as well as competitive products; ▪ the potential and perceived advantages of our product candidate over alternative treatments; ▪ the degree of cost- effectiveness of our product candidate; ▪ availability of alternative therapies at similar or lower cost, including generic and over- the- counter products; ▪ the extent to which any product candidate is approved for inclusion on formularies of hospitals and managed care organizations; ▪ whether the product is designated under physician treatment guidelines as a first- line therapy or as a second or third- line therapy for particular indications; ▪ whether our product candidate can be used effectively with other therapies to achieve higher response rates; ▪ adverse publicity about our product candidate or favorable publicity about competitive products; ▪ the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ▪ the approval of other new therapies for the same indications; ▪ relative convenience and ease of administration of our product candidates; and ▪ potential product liability claims. If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and third- party payors, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may never be successful. We may be unsuccessful, in obtaining or may be unable to maintain the benefits associated with, orphan drug designation for current or future product candidates that we may develop. If our competitors are able to obtain orphan product exclusivity for their products in specific indications, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States. We may elect to seek Orphan Drug Designation for certain indications for our product candidates. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. Generally, if a product candidate with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for seven years. Therefore, if our competitors are able to obtain orphan product exclusivity for their product candidates in the same indications we are pursuing, we may not be able to have competing products approved in those indications by the applicable regulatory authority for a significant period of time. There are also limited circumstances where the FDA may reduce the seven- year exclusivity for a product candidate with an orphan drug designation where other product candidates show clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Historically, development of IgM antibodies has been limited by difficulties in recombinant expression and manufacture of these antibodies; therefore, the FDA may determine that we cannot assure the availability of sufficient quantities of our product candidates to the extent necessary to support marketing exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product **. In Catalyst Pharms., Inc. v. Becerra, 14 F. 4th 1299 (11th Cir. 2021), the court disagreed with the FDA' s longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of the orphan drug exclusivity. However, in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court' s order in Catalyst, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the Catalyst order – that is, the agency will continue tying the scope of orphan- drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity** . Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and approval standards. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed. Reimbursement decisions by third- party payors may have an adverse effect on pricing and market acceptance. If reimbursement is not available or is not sufficient for our products, it is less likely that our products will be widely used. Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Third- party payors, such as government healthcare programs, private health insurers and health maintenance organizations, decide which drugs they will cover and establish the level of reimbursement for such drugs. One third- party payor' s determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. We cannot be certain that coverage and reimbursement will be available or adequate for any products that we develop. If coverage and adequate reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our product candidates, if approved. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator' s costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future change to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement from third- party payors, including both government- funded and private payors, for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition. If the market opportunities for any product that we develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer. We focus our product candidate development on therapeutic IgM antibodies. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, physician interviews, patient foundations and market research, and may prove to be incorrect. Further, new developments, such as the development of vaccines or new therapeutics, may change the estimated incidence or prevalence of the diseases targeted by our programs. The number of patients may turn out to be lower than expected. If any of the foregoing estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business. The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small. The FDA often approves new cancer therapies only for use after one or more other treatments have failed. When cancer is detected early enough, first- line therapy, such as chemotherapy, hormone therapy or surgery, is sometimes adequate to treat the patient. If first- line therapy proves unsuccessful, second- line therapies, such as additional chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these therapies, may be administered. Third- or fourth- line therapies may include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. We have in the past sought approval through clinical testing for certain product candidates for patients who have failed one or more approved treatments, and may do so again in the future. Even if we obtain regulatory approval and significant market share for such product candidates, because the potential target population may be small, we may never achieve profitability without obtaining regulatory approval for additional indications. In addition, there is no guarantee that any of our product candidates, even if approved, would be approved as a particular line of treatment. In addition, even if any of our product candidates were approved for a particular line of treatment, we would likely have to conduct additional clinical trials prior to gaining approval as an earlier line of treatment. Development of product candidates in combination with other therapies could expose us to additional risks. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially. We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any other product candidate, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop. Additionally, if the third- party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Even if we receive regulatory approval to commercialize any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which will result in significant additional expense. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, and may contain requirements for potentially costly post-approval trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the marketed product. For any approved product, we will be subject to ongoing regulatory obligations and extensive oversight by regulatory authorities, including with respect to manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with cGMP and current good clinical practices (cGCP) for any clinical trials that we conduct post- approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with 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; ▪ adverse publicity, fines, warning letters or holds on clinical trials; ▪ refusal by the FDA, EMA or another applicable regulatory authority to approve pending applications or supplements to approved applications filed by us, or 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. Further, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians may prescribe, in their independent professional medical judgment, products for off- label uses as the FDA does not regulate the behavior of physicians in their choice of drug treatments, the FDA does restrict manufacturer' s communications on the subject of off- label use of their products. Companies may only share truthful and not misleading information that is otherwise consistent with a product' s FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses and a company that is found to have improperly promoted off- label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined companies from engaging in off- label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Further, the FDA' s or comparable foreign regulatory authorities' 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, which would adversely affect our business, prospects and ability to generate revenue or achieve or sustain profitability. If any product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and we will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in: ▪ decreased demand for any future approved products; ▪ injury to our reputation; ▪ withdrawal of clinical trial participants; ▪ termination of clinical trial sites or entire trial programs; ▪ increased regulatory scrutiny, including investigations by the FDA and other regulators of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs; ▪ significant litigation costs; ▪ substantial monetary awards to or costly settlement with patients or other claimants; ▪ product recalls, a change in the indications for which they may be used or suspension or withdrawal of marketing approvals; ▪ loss of revenue; ▪ diversion of management and scientific resources from our business operations; and ▪ the inability to commercialize our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations. We may need to have in place increased product liability coverage if and when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation. Our product candidates, for which we intend to seek approval, may face competition sooner than anticipated. Our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of biosimilar products. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA), created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the ACA, a manufacturer may submit an application for licensure of a biologic product that is " biosimilar to " or " interchangeable with " a previously approved biological product or " reference product. " Under this statutory scheme, an application for a biosimilar product may not be submitted to the FDA until four years following approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full ~~Biologics License Application (~~ BLA ~~)~~ for such product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, efficacy and potency of their product. Furthermore, recent legislation has proposed that the 12- year exclusivity period for a referenced product may be reduced to seven years. Foreign governments tend to impose strict price controls, which may adversely affect our future profitability. In most foreign countries, particularly those in the European Union, prescription drug pricing and reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidates to other available therapies. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenue that are generated from the sale of the product in that country. If reimbursement of such product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross- border sales, our profitability will be negatively affected . We will need to grow our...... a material adverse effect on our business . Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates, if approved, and affect the prices we may obtain. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change healthcare systems in ways that could affect our ability to sell any of our product candidates profitably, if such product candidates are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including proposals aimed at lowering prescription drug prices and increasing competition for prescription drugs, as well as additional regulation on pharmaceutical transparency and reporting requirements, any of which could negatively impact our future profitability and increase our compliance burden. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: ▪ The demand for our product candidates, if approved; ▪ Our ability to set a price that we believe is fair for our products; ▪ Our ability to obtain coverage and reimbursement approval for a product; ▪ Our ability to generate revenue and achieve or maintain profitability; ▪ The level of taxes that we are required to pay; and ▪ The availability of capital. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. In March 2010, the ACA was enacted, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the United States pharmaceutical industry. Among the provisions of the ACA of importance to the pharmaceutical industry are the following: ▪ an annual, non- deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; ▪ an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23. 1 % and 13 % of the average manufacturer price (AMP), for most branded and generic drugs, respectively; ▪ Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 % point- of- sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; ▪ extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; ▪ expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133 % of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability; ▪ requirement that applicable manufacturers and group purchasing organizations report annually to the Centers for Medicare & Medicaid Services (CMS), information regarding certain payments and other transfers of value given to physicians and teaching hospitals, and any ownership or investment interest that physicians, or their immediate family members, have in their company; ▪ a requirement that manufacturers and authorized distributors of applicable drugs annually report information related to samples provided to practitioners; ▪ expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti- Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance; ▪ a licensure framework for follow- on biologic products; ▪ a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and ▪ establishment of a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Since its enactment, there remain judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U. S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments will remain in effect through ~~2031~~ **2032** , with the exception of a temporary suspension implemented under various COVID- 19 relief legislation ~~from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments can vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester~~ . Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. 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. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. ~~Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. The HHS has released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles.~~ In August 2022, Congress passed the **IRA** ~~Inflation Reduction Act of 2022~~ , which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high- priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out- of- pocket prescription drug costs for beneficiaries, among other changes. **Various industry stakeholders, including the U. S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional.** The impact of these **judicial challenges as well as future** legislative, executive, and administrative actions ~~and any future healthcare measures~~ and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the **IRA** ~~Inflation Reduction Act~~ , as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved **. Uncertainties created by the IRA and other cost containment measures may negatively impact potential investments, company valuation, royalty- based**

**earnings, mergers and acquisitions in our industry** . Complying with any new legislation and regulatory changes could be time- intensive and expensive, resulting in a material adverse effect on our business. In the European Union similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost- effective by third- party payors, an adequate level of reimbursement might not be available for such products and third- party payors' reimbursement policies might adversely affect our ability to sell any future products profitably. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- approval testing and other requirements. 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, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, including delays or disruptions due to the COVID- 19 pandemic, travel restrictions, staffing shortages, may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business ~~. For example, in 2018 and 2019, the U. S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA worked to resume normal operations. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. While the FDA has largely caught up with domestic preapproval inspections, it continues to work through its backlog of foreign inspections. However, the FDA may not be able to continue its current inspection pace, and review timelines could be extended, including where a pre- approval inspection or an inspection of clinical sites is required and due to the ongoing COVID- 19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic and may experience delays in their regulatory activities~~ . If a prolonged government shutdown or disruption occurs, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions and provide feedback on our clinical development plans, which could have a material adverse effect on our business and our anticipated timelines. Further, in our operations as a public company, future government shutdowns or other disruptions to normal operations could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Our business may become subject to economic, political, regulatory and other risks associated with international operations. Our business may be subject to risks associated with conducting business internationally. Some of our clinical trial sites as well as some of our suppliers and collaborators, are located outside of the United States. We may also enter into additional non- U. S markets. Accordingly, our future results could be harmed by a variety of factors, including: ▪ economic weakness, including inflation, or political instability in particular foreign economies and markets; ▪ differing regulatory requirements for drug approvals in foreign countries; ▪ potentially reduced protection for intellectual property rights; ▪ difficulties in compliance with non- U. S. laws and regulations; ▪ changes in non- U. S. regulations and customs, tariffs and trade barriers; ▪ changes in non- U. S. currency exchange rates and currency controls; ▪ changes in a specific country' s or region' s political or economic environment; ▪ trade protection measures, import or export licensing requirements or other restrictive actions by U. S. or non- U. S. governments; ▪ differing reimbursement regimes, including price controls; ▪ negative consequences from changes in tax laws; ▪ compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ▪ workforce uncertainty in countries where labor unrest is more common than in the United States; ▪ difficulties associated with staffing and managing foreign operations, including differing labor relations; ▪ production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ▪ business interruptions resulting from geo- political actions, including war (such as the ongoing conflict between Russia and Ukraine) and terrorism, ~~or~~ natural disasters ~~including earthquakes~~ , ~~typhoons, floods and fires,~~ or **public** ~~outbreaks of~~ health ~~epidemics~~ **emergencies** such as the COVID- 19 pandemic. Our business and current and future relationships with customers and third- party payors in the United States and elsewhere will be subject, directly or indirectly, to applicable federal and state anti- kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings. Healthcare providers, physicians and third- party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third- party payors and other entities may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti- Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we conduct clinical research on product candidates and market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal government and by the U. S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include, but are not limited to, the following: ▪ the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid; ▪ federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private citizens on behalf of the government, through civil whistleblower, or qui tam actions, and the federal civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities, among other things, for knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government; ▪ HIPAA, which among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters; ▪ HIPAA, as amended by HITECH, and its implementing regulations, which imposes certain obligations, including mandatory contractual terms on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that create, receive, maintain or transmit individually health information for or on behalf of a covered entity and their subcontractors that use, disclose or otherwise process individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ▪ the federal Open Payments program under the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) and applicable group purchasing organizations to report annually to CMS information related to " payments or other transfers of value " made to covered recipients, such as physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, and information regarding ownership and investment interests held by physicians (as defined above) and their immediate family members. The information reported annually is publicly available on a searchable website **;** ▪ analogous state and foreign laws and regulations, including: state anti- kickback and false claims laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non- governmental third- party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that require drug manufacturers to report information relating to pricing and marketing information; and ▪ state and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre- empted by HIPAA, thus complicating compliance efforts Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the U. S. federal Anti- Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other providers or entities with whom we expect to do business, is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation 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 employees, independent contractors, principal investigators, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants and vendors, could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor 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. We have adopted a written code of business conduct and ethics, but it is not always possible to identify and deter employee or independent contractor 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental 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. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood- borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the State of California to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. Current or future laws and regulations may impair our research, development or commercialization efforts. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations. Business or economic disruptions could seriously harm...... by us could harm our business. Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant losses since our inception. Our net loss for the years ended December 31, **2023,** 2022, **and** 2021 ~~, and 2020~~ was $ **246. 4 million, $** 221. 1 million, **and** $ 165. 2 million, ~~and $ 81. 4 million,~~ respectively. As of December 31, ~~2022~~ **2023** , our accumulated deficit was approximately $ ~~574~~ **821** . ~~8~~ **2** million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved product candidates and add infrastructure and personnel to support our product development efforts and operations as a public company. Historically we have financed our operations primarily through the sale of equity and debt securities as well as funding received from our collaboration partners. We do not generate any revenue from product sales and our product candidates will require substantial additional investment before they may provide us with any revenue, if ever. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. The net losses we incur may fluctuate significantly from quarter- to- quarter such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate product revenue or achieve profitability. For example, our expenses could increase if we are required by the FDA to perform clinical trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates ~~. Drug development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives~~ . Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, developing our in- house manufacturing capabilities, hiring personnel, raising capital and providing general and administrative support for these operations. Since 2010, such activities have exclusively related to the research, development and manufacture of IgM antibodies and to building our proprietary IgM antibody technology platform. We are still in the early stages of developing our product candidates, and we have not completed development of any product candidate. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Our ability to generate revenue and achieve profitability depends in large part on our ability, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenue from sales of products for the foreseeable future. To generate product revenue and become and remain profitable, we must succeed in developing and commercializing product candidates with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including: ▪ successfully completing preclinical and clinical development of our product candidates in a timely manner; ▪ obtaining regulatory approval for such product candidates in a timely manner; ▪ satisfying any post- marketing approval commitments required by applicable regulatory authorities; ▪ developing an efficient, scalable and compliant manufacturing process for such product candidates, including expanding and maintaining manufacturing operations, commercially viable supply and manufacturing relationships with third parties to obtain finished products that are appropriately packaged for sale; ▪ successfully launching commercial sales following any marketing approval, including the development of a commercial infrastructure, whether in- house or with one or more collaborators; ▪ maintaining a continued acceptable safety profile following any marketing approval; ▪ achieving commercial acceptance of such product candidates as viable treatment options by patients, the medical community and third- party payors; ▪ addressing any competing technological and market developments; ▪ identifying, assessing, acquiring and developing new product candidates; ▪ obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally; ▪ protecting our rights in our intellectual property portfolio, including our licensed intellectual property; ▪ negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidates; and ▪ attracting, hiring and retaining qualified personnel. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. ~~We will require substantial additional funding to finance our operations, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back or cease our product development programs or operations.~~ All of our product candidates and discovery programs are in preclinical development or early stage clinical development. Developing drug products, including conducting preclinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates, which will increase our expenses. We will continue to require additional funding to complete the development and commercialization of our product candidates, to continue to advance our discovery programs, to expand our manufacturing facilities and to satisfy additional costs that we have incurred and expect to continue to incur in connection with operating as a public company. Such funding may not be available on acceptable terms or at all. As of December 31, ~~2022~~ **2023** , we had $ ~~427~~ **337** . ~~2~~ **7** million in cash, cash equivalents, and marketable securities. We believe that our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least one year past the issuance date of the consolidated financial statements included elsewhere in this Annual Report on Form 10- K. Our estimate as to how long we expect our cash, cash equivalents, and marketable securities to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. In addition, because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates. Our future funding requirements will depend on many factors, including but not limited to: ▪ the initiation, scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities for our product candidates; ▪ the costs associated with manufacturing our product candidates, including expanding our own manufacturing facilities, and establishing commercial supplies and sales, marketing and distribution capabilities; ▪ the timing and cost of capital expenditures to support our research, development and manufacturing efforts; ▪ the number and characteristics of other product candidates that we pursue; ▪ the costs, timing and outcome of seeking and obtaining FDA and non- U. S. regulatory approvals; ▪ our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights; ▪ the timing, receipt and amount of sales from our potential products; ▪ our need and ability to hire additional management, scientific and medical personnel; ▪ the effect of competing products that may limit market penetration of our product candidates; ▪ our need to implement additional internal systems and infrastructure, including financial and reporting systems; ▪ the economic and other terms, timing and success of any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements; ▪ the impact of macroeconomic conditions, including inflation, supply chain disruption and volatility in the capital markets, on our business, financial condition and results of operations; ▪ the compliance and administrative costs associated with being a public company; and ▪ the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions. Until we can generate **enough** ~~a sufficient amount of~~ product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through one or more public and private equity offerings, debt financings and strategic partnerships. We do not have any committed external source of funds. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our clinical or discovery programs or our business operations. Raising additional capital may cause dilution to...... our current or future operating plans. Unstable market and economic conditions may have serious adverse consequences on our business and financial condition. Global credit and financial markets have experienced extreme disruptions at various points over the last few decades, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. For example, ~~the current~~ **ongoing armed** ~~conflict~~ **conflicts have** ~~between Ukraine and Russia has~~ created volatility in the capital markets and ~~is~~ **are** expected to have further global economic consequences. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget. At December 31, ~~2022~~ **2023** , we had $ ~~427~~ **337** . ~~2~~ **7** million of cash, cash equivalents, and marketable securities. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, ~~2022~~ **2023** , no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and general economic downturn. ~~rely on other third parties for the manufacture of our product candidates and to conduct clinical trials,and similar events relating to their computer systems could also have a material adverse effect on our business~~ **Business or economic disruptions** ~~.Our operations are vulnerable to interruption by catastrophic events,which~~ could **seriously** harm our business and financial condition **and increase our costs and expenses** .Our operations,and those of our CROs,clinical trial sites,suppliers,regulators,and other third parties with whom we engage,could be subject to **earthquakes** ~~natural disasters~~ ,power ~~outages~~ **shortages** ,telecommunications failures,failures or breaches of information technology systems, **water shortages,floods,hurricanes,typhoons,fires,extreme weather conditions,** epidemics,pandemics **such as the COVID- 19 pandemic** ,and other natural or man- made disasters or business interruptions.The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.We currently rely on third party manufacturers to produce and process our product candidates.Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption.We cannot presently predict the scope and severity of any potential business shutdowns or disruptions,but if we or any of the third parties with whom we engage,including the suppliers,CROs,clinical trial sites,regulators and other third parties with whom we conduct business,were to experience shutdowns or other business disruptions,our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.All of our operations are located in Mountain View,California and Doylestown,Pennsylvania,with our corporate headquarters in Mountain View,California.Damage or extended periods of interruption to our facilities due to fire,natural disaster,power loss,communications failure,unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates.We do not carry sufficient insurance to compensate us for actual losses from interruption of our business that **may occur,and any losses or damages incurred by us could harm our business.** Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited ~~. As of December 31, 2022, we had net operating loss (NOL) carryforwards available to reduce future taxable income, if any, for federal and state income tax purposes of approximately $ 261. 1 million and $ 365. 2 million, respectively. At December 31, 2022, we also had federal and California research and development tax credit carryforwards of $ 25. 1 million and $ 14. 0 million, respectively, available to offset future income tax, if any~~ . Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an " ownership change, " the corporation' s ability to use its NOLs and other pre- change tax attributes such as research tax credits to offset its post- change taxable income or taxes may be limited. In general, an " ownership change " occurs if there is a cumulative change in our ownership by " 5 % shareholders " that exceeds 50 percentage points over a rolling three- year period. We completed a Section 382 study and believe we have experienced at least two changes in ownership. Consequently, we may be limited in our ability to use our NOL carryforwards and other tax assets in a future year if taxable income in that given year exceeds our cumulative 382 NOL utilization limits through that specific year. As a result, even if we attain profitability, it is possible 382 limitations on the ability to use our NOL carryforwards and other tax assets could adversely affect our future cash flows. In addition, our NOL carryforwards may be unavailable to offset future taxable income because of restrictions under U. S. tax law. The Tax Cuts and Jobs Act of 2017 (Tax Act), as modified by the CARES Act, imposes certain limitations on the deduction of NOLs, including a limitation on use of NOLs generated in tax years that began on or after January 1, 2018 to offset 80 % of taxable income in tax years beginning on or after January 1, 2021. Changes in the U. S. taxation of international business activities or the adoption of other tax reform policies could materially impact our business, results of operations and financial condition. Changes to U. S. tax laws that may be enacted in the future could impact the tax treatment of our foreign earnings. If we expand our international business activities, any changes in the U. S. or foreign taxation of such activities may increase our worldwide effective tax rate and adversely affect our business, results of operations and financial condition. For example, the Organization for Economic Cooperation and Development has proposed implementing a global minimum tax of 15 %, **referred to as Pillar 2,** which has been agreed to by over 136 countries **. Pillar 2 was adopted by the European Union for implementation by its member states into national legislation by the end of 2023 and may be adopted by other jurisdictions** . In addition, on January 1, 2022, a provision of the Tax Cuts and Jobs Act of 2017 went into effect that eliminates the option to deduct domestic research and development costs in the year incurred and instead requires taxpayers to amortize such costs over five years. In 2022, the United States also enacted the **IRA** ~~Inflation Reduction Act~~ , which imposes, among others, a 1 % excise tax on certain repurchases of stock and a 15 % alternative minimum income tax on " adjusted financial statement income " of certain corporations. Such changes, among others, may adversely affect our effective tax rates, cash flows and general business condition. Acquisitions or joint ventures could increase our capital requirements, disrupt our business, cause dilution to our stockholders, cause us to incur debt or assume contingent liabilities and otherwise harm our business. We evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including: ▪ disruption in our relationships with any strategic partners or suppliers as a result of such a transaction; ▪ the assumption of additional indebtedness or contingent or otherwise unanticipated liabilities related to acquired companies; ▪ the issuance of our equity securities; ▪ difficulties integrating acquired personnel, technologies and operations into our existing business; ▪ retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships; ▪ diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges; ▪ risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; ▪ increases in our expenses and reductions in our cash available for operations and other uses; ▪ our inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and ▪ possible write- offs or impairment charges relating to acquired businesses. Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. Future credit arrangements may restrict our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write- offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. Moreover, we may not be able to identify suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Adverse events or perceptions affecting the financial services industry could adversely affect our operating results, financial condition and prospects. Limited liquidity, defaults, non- performance or other adverse developments affecting financial institutions or parties with which we do business, or perceptions regarding these or similar risks, have in the past and may in the future lead to market- wide liquidity problems. Such developments, and their effects on the broader financial system, could result in a variety of material and adverse impacts on our business operations and financial conditions, including, but not limited to: ▪ delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; ▪ loss of access to revolving existing credit facilities or other working capital sources or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; ▪ potential or actual breach of obligations, including U. S. federal and state wage laws and contracts that may require us to maintain letters or credit or other credit support arrangements; and ▪ termination of cash management arrangements or delays in accessing or actual loss of funds subject to cash management arrangements. ~~For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed and placed in receivership and subsequently, additional financial institutions have been placed into receivership. Prior to SVB' s closure, we had less than $ 5. 0 million in uninsured deposit accounts with SVB. As a result of U. S. government intervention, we subsequently regained access to our accounts at SVB, including the uninsured portion of deposit accounts. However, there remains significant uncertainty surrounding the resolution of SVB and the impact of SVB' s closure on the broader financial system. Moreover, there is no guarantee that the U. S. government will intervene to provide access to uninsured funds in the future in the event of the failure of other financial institutions, or that they would do so in a timely fashion.~~ In such an event, parties with which we have commercial agreements, including collaboration partners and suppliers, may be unable to satisfy their obligations to, or enter into new commercial arrangements with, us. Concerns regarding the U. S. or international financial systems could impact the availability and cost of financing, thereby making it more difficult for us to acquire financing on acceptable terms or at all. In addition, instability in the financial services industry could spur a deterioration in the macroeconomic environment. Any of these risks could materially impact our operating results, liquidity, financial condition and prospects. Risks Related to Our Dependence on Third Parties We currently rely on third parties to manufacture and deliver our product candidates and provide other services. Any failure by one of these third parties to manufacture and deliver acceptable product candidates and provide other services for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products. We currently have limited in- house manufacturing experience and personnel. While we operate a cGMP manufacturing facility for the manufacture of clinical trial drug materials, we expect to continue to rely for some time on third parties to manufacture our product candidates and for the commercial manufacture of some or all of our product candidates, if approved. Bulk drug substance (BDS) for our clinical- stage product candidates is provided from both internal and third- party contract manufacturers. Any reduction or halt in supply of BDS could severely constrain our ability to develop our product candidates until a replacement contract manufacturer is found and qualified. As a result of supply chain constraints and staffing issues at one of our contract manufacturers, we have previously adjusted the anticipated filing date of our IND application for **one of** ~~IGM- 7354 and we have had to make certain other adjustments, and we may have to make further adjustments in the future, with respect to this or~~ **our** ~~other programs~~ **clinical candidates** . In addition, we currently rely on a third- party contract research organization for the conduct of our clinical assays and we have experienced, and may continue to experience, delays and interruptions, as well as quality and design errors, in this supply of information to us. If we are unable to arrange for and maintain such third- party manufacturing and analytical sources that are capable of meeting regulatory standards, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or clinical sample analysis data, or we may be delayed in doing so. If we are unable to arrange for and maintain such third- party manufacturing sources that are capable of meeting regulatory standards, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. A loss of supply of our product candidates, for any reason, including as a result of manufacturing, supply or storage issues, damaged shipments, or otherwise, could result in us experiencing further delays, or disruptions, suspensions or terminations of, or being required to restart or repeat, any pending or ongoing clinical trials. Such failure or substantial delay or loss of supply could materially harm our business. Reliance on third- party manufacturers entails risks to which we may not be subject if we manufactured product candidates ourselves, including: ▪ the possible failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third- party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them; ▪ reliance on the third party for regulatory compliance and quality control and assurance and failure of the third party to comply with regulatory requirements; ▪ the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture our product candidates in accordance with our product specifications); ▪ the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified; ▪ the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; ▪ the possible misappropriation of our proprietary information, including our trade secrets and know- how; and ▪ the possibility of termination or nonrenewal of the agreement by the third- party at a time that is costly or damaging to us. In addition, the FDA, EMA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in sanctions being imposed on us, including fines, injunctions, civil penalties, restrictions on the product or on the manufacturing or laboratory facility, including license revocation, marketed product recall, suspension of manufacturing, product seizure, voluntary withdrawal of the product from the market, operating restrictions or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations. We may have little to no control regarding the occurrence of third- party manufacturer incidents. Any failure by our third- party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, would lead to a delay in, or failure to seek or obtain, regulatory approval of any of our product candidates. Furthermore, any change in manufacturer of our product candidates or approved products, if any, would require new regulatory approvals, which could delay completion of clinical trials or disrupt commercial supply of approved products. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third party and a feasible alternative many not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order 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. 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 rely on third parties to monitor, support, conduct and oversee clinical trials of the product candidates that we are developing and, in some cases, to maintain regulatory files for those product candidates. We may not be able to obtain regulatory approval for our product candidates or commercialize any products that may result from our development efforts, or may miss expected deadlines, if we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as contractually required, or if these third parties fail to timely transfer any regulatory information held by them to us. We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third- party strategic partners, to monitor, support, conduct and oversee preclinical studies and clinical trials of our current and future product candidates. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA, EMA or other regulatory agencies. Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with cGCP regulations and guidelines enforced by the FDA, the competent authorities of the member states of the European Union and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA could determine that any of our clinical trials fail or have failed to comply with applicable cGCP regulations. In addition, our clinical trials must be conducted with product produced under the cGMP regulations enforced by the FDA, and our clinical trials may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and increase our costs. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. If any of our clinical trial sites terminate for any reason, we may experience the loss of follow- up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. Further, our CROs are not required to work indefinitely or exclusively with us. Our existing agreements with our CROs may be subject to termination by the counterparty upon the occurrence of certain circumstances. If any CRO terminates its agreement with us, the research and development of the relevant product candidate would be suspended, and our ability to research, develop, and license future product candidates may be impaired. We may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us. Switching or adding CROs or other suppliers can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or supplier commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business. We rely on third parties for various operational and administrative aspects of our business, including for certain cloud- based software platforms, which impact our financial, operational and research activities. If any of these third parties fail to provide timely, accurate and ongoing service or if the technology systems and infrastructure suffer outages that we are unable to mitigate, our business may be adversely affected. We currently rely upon third party consultants and contractors to provide certain operational and administrative services. These services include tax advice and clinical and research consultation. The failure of any of these third parties to provide accurate and timely service may adversely impact our business operations. In addition, if such third- party service providers were to cease operations, temporarily or permanently, face financial distress or other business disruption, increase their fees or if our relationships with these providers deteriorate, we could suffer increased costs until an equivalent provider could be found, if at all, or we could develop internal capabilities, if ever. In addition, if we are unsuccessful in choosing or finding high- quality partners, if we fail to negotiate cost-effective relationships with them, or if we ineffectively manage these relationships, it could have an adverse impact on our business and financial performance. Further, our operations depend on the continuing and efficient operation of our information technology, communications systems and infrastructure, and on " cloud- based " platforms. Any of these systems and infrastructure are vulnerable to damage or interruption from earthquakes, vandalism, sabotage, terrorist attacks, floods, fires, power outages, telecommunications failures, and computer viruses or other deliberate attempts to harm the systems. The occurrence of a natural or intentional disaster, any decision to close a facility we are using without adequate notice, or particularly an unanticipated problem at a cloud- based virtual server facility, could result in harmful interruptions in our service, resulting in adverse effects to our business. Strategic partnerships may be important to us. We will face significant competition in seeking new strategic partners. We have limited capabilities for drug development and manufacturing and do not yet have any capability for sales, marketing or distribution. For some of our product candidates, we may determine to collaborate with pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. For example, we have entered into a collaboration with Sanofi for the development and potential commercialization of certain therapeutic products. The competition for strategic partners is intense. Our ability to reach a definitive agreement for 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 comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The strategic partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such collaboration could be more attractive than the one with us for our product candidate. Strategic partnerships are complex and time- consuming to negotiate and document. 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. Even if we are successful in entering into collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements with other potential collaborators. If we are unable to reach agreements with suitable strategic partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into strategic partnerships and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our therapeutic platforms and our business may be materially and adversely affected. Any 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 partner terminates the collaboration. Any such collaboration, or other strategic transaction, may require us to incur non- recurring or other charges, and increase our near- and long- term expenditures and pose significant integration or implementation challenges or disrupt our management or business. 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 have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any 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 the market. If we are unable to maintain strategic partnerships, or if these strategic partnerships are not successful, our business could be adversely affected. Any strategic partnerships we enter into may pose a number of risks, including the following: ▪ we may not be able to enter into critical strategic partnerships or enter them on favorable terms; ▪ strategic partners have significant discretion in determining the effort and resources that they will apply to such a partnership, and they may not perform their obligations as agreed or expected; ▪ strategic partners may decide not to pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; ▪ strategic partners 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; ▪ strategic partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the strategic partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than our product candidates; ▪ strategic partners may restrict us from researching, developing or commercializing certain products or technologies without their involvement; ▪ product candidates discovered in collaboration with us may be viewed by our strategic partners as competitive with their own product candidates or products, which may cause strategic partners to cease to devote resources to the commercialization of our product candidates; ▪ a strategic partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidates; ▪ disagreements with strategic partners, including disagreements over proprietary rights, ownership of intellectual property, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; ▪ strategic partners may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights relating to our product candidates or discovery programs 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 potential litigation or other intellectual property related proceedings; ▪ strategic partners may own or co- own intellectual property covering our product candidates or discovery programs that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates or discovery programs; ▪ we may need the cooperation of our strategic partners to enforce or defend any intellectual property we contribute to or that arises out of our strategic partnerships, which may not be provided to us; ▪ strategic partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; ▪ strategic partners may control certain interactions with regulatory authorities, which may impact our ability to obtain and maintain regulatory approval of our product candidates; ▪ we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control; ▪ strategic partners may grant sublicenses to our technology or product candidates or undergo a change of control and the sublicensees or new owners may decide to take the collaboration in a direction which is not in our best interest; ▪ strategic partners may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know- how or intellectual property of the strategic partner relating to our product candidates or discovery programs; ▪ strategic partnerships may require us to incur short and long- term expenditures, issue securities that dilute our stockholders or disrupt our management and business; ▪ if our strategic partners do not satisfy their obligations under our agreements with them, or if they terminate our strategic partnerships with them, we may not be able to develop or commercialize product candidates as planned; ▪ strategic partners may require us to share in development and commercialization costs pursuant to budgets that we do not fully control and our failure to share in such costs could have a detrimental impact on the strategic partnership or our ability to share in revenue generated under the strategic partnership; ▪ strategic partnerships may be terminated for the convenience of the partner and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; and ▪ strategic partnership or collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future strategic partner ours were to be involved in a business combination, the continued pursuit and emphasis on our development or commercialization program under such collaboration could be delayed, diminished, or terminated. In March 2022, we entered into the Sanofi Agreement , pursuant to which we ~~will~~ collaborate with Sanofi to generate, develop, manufacture and commercialize IgM antibodies directed to six primary targets, three of which are intended as oncology targets and three of which are intended as immunology targets. Risks Related to Our Intellectual Property Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale , or import our future approved products or impair our competitive position. Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. We are aware of third - party patents and patent applications containing claims directed to most of our areas of product development, which patents and applications could potentially be construed to cover our product candidates and the use thereof to treat patients. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. There is no assurance that third- party patents or patent applications of which we are aware may not ultimately be found to limit our ability to make, use, sell, offer for sale , or import our future approved products or impair our competitive position, even though we do not believe they are relevant to our business. Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. These patents may not expire before we receive marketing authorization for our product candidates, and they could delay the commercial launch of one or more future products. If our products were to be found to infringe any such patents, and we were unable to invalidate those patents, or if licenses for them are not available on commercially reasonable terms, or at all, our business, financial condition , and results of operations could be materially harmed. Furthermore, even if a license is available, it may be non- exclusive, which could result in our competitors gaining access to the same intellectual property. Our failure to maintain a license to any technology that we require may also materially harm our business, financial condition , and results of operations, and we would be exposed to a threat of litigation. In the biotechnology industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace both within and outside the United States including patent infringement lawsuits, oppositions, inter partes review (IPR) and post- grant review (PGR) proceedings before the United States Patent and Trademark Office (USPTO), or the applicable foreign patent counterpart. The types of situations in which we may become a party to such litigation or proceedings relating to third party intellectual property include: ▪ we or our licensors may initiate litigation or other proceedings, including post- grant proceedings such as oppositions, IPRs or PGRs, against third parties seeking to invalidate the patents held by those third parties, to obtain a judgment that our products or processes do not infringe those third parties' patents or to obtain a judgment that those parties' patents are invalid and / or unenforceable; ▪ if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third- party with a dominant patent position; ▪ if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we will need to defend against such proceedings; and ▪ if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and / or that we breached our obligations under the license agreement, and we would need to defend against such proceedings. These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. There is a risk that a court would decide that we are infringing the third party' s patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us to pay third party damages or some other monetary award, depending upon the jurisdiction. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties, potentially including treble damages and attorneys' fees if we are found to have willfully infringed, and we may be required to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. 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 a material adverse effect on our ability to raise additional funds or on our business, results of operations, financial condition **,** and prospects. Any of these outcomes could have a material adverse effect on our business. If we are unable to obtain, maintain and enforce patent and trade secret protection for our product candidates and related technology, our business could be materially harmed. Our strategy depends on our ability to identify, seek, obtain **,** and maintain patent protection for our discoveries. Our patent portfolio is relatively small compared to many large and more established pharmaceutical and biotechnology companies that have patent portfolios consisting of hundreds, and in some case even thousands, of granted patents. As our patent portfolio grows, we expect patent protection will continue to be an important part of our strategy. The patent protection process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we have licensed from third parties. Therefore, our owned, co- owned, or in- licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. The patent applications that we own, or co- own, or in- license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries or that effectively prevent third parties from commercializing competitive product candidates. Moreover, the patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. We may be subject to a third- party preissuance submission of prior art to the USPTO or a foreign jurisdiction, and such prior art may affect the scope of any claims we ultimately get allowed or it may prevent our patent applications from issuing as patents. Further, the issuance of a patent does not ensure that it is valid or enforceable, nor is the issuance conclusive as to inventorship or the scope of any claims. Third parties may challenge the validity, enforceability or scope of our issued patents or claim that they should be inventors on such patents, and such patents may be narrowed, invalidated, circumvented, or deemed unenforceable, or such third parties may gain rights to such patents. We could also become involved in reexamination, inter **-** parties review, post- grant review, opposition or derivation proceedings, challenging our patent rights or the patent rights of others. In addition, **recent** changes in law **, such as the U. S. Supreme Court' s decision in Amgen Inc. v. Sanofi, have introduced changes in the law relevant to biotechnology patents, and future changes in law** may **further** introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. If ~~,~~our patents are narrowed, invalidated **,** or held unenforceable, third parties may be able to commercialize our technology or products and compete directly with us without payment to us. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Furthermore, even if our patents are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims **,** or provide us with a competitive advantage. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the issuance, validity, enforceability, scope **,** and commercial value of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own, co- own, or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology. Moreover, some of our owned or in- licensed patents and patent applications are or may in the future be co- owned with third parties. If we are unable to obtain an exclusive license to any such third **-** party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third- parties, including our competitors, and our competitors could market competing products and technology. We may need the cooperation of any such co- owners of our patents to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business prospects and financial conditions. **Intellectual property discovered through government funded programs may be subject to federal regulations such as" march- in" rights, certain reporting requirements and a preference for United States- based companies.**

**Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- United States manufacturers.** In ~~addition,~~ the **future, we may obtain funding, in part, from U. S. federal or state governments for** research ~~resulting~~ **we conduct, and such funding may be used** in ~~certain~~ **the advancement** of **our existing technologies** ~~our~~ - **or creation of additional** in- licensed patent rights and technology ~~was funded in part by the U~~ . ~~S. federal or state~~ **Pursuant to the Bayh- Dole Act of 1980, the United States** ~~governments~~ - **government has certain rights in inventions developed with government funding, including a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose** . As a result, the U. S. government may have certain rights, including so- called march- in rights, to ~~such~~ **any future** patent rights **funded in part by the U. S. federal government** and any products or technology developed from such patent rights. ~~When new technologies are developed with U. S. government funding, the U. S. government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the U. S. government to use the invention for non- commercial purposes.~~ These rights may permit the U. S. government to disclose our confidential information to third parties and to exercise march- in rights to use or to allow third parties to use our licensed technology **, and there can be no assurance that we would receive compensation from the U. S. government for the exercise of such rights** . The U. S. government can exercise its march- in rights if it determines that action is necessary because we fail to achieve the practical application of 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 exercise by the U. S. government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. If we fail to comply with our obligations under any license, collaboration or other intellectual property- related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or product candidates or we could lose certain rights to grant sublicenses. We in- license certain patent rights and proprietary technology from third parties that are important to our discovery platform and development of product candidates. ~~For example, in October 2020, the Company entered into a multi- year patent and materials license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas Health Science Center at Houston for certain antibodies against the SARS- CoV- 2 virus.~~ In January 2021, **we** ~~the Company~~ entered into an exclusive license agreement with Medivir AB (Medivir) through which **we** ~~the Company~~ received global, exclusive development and commercialization rights for birinapant, a clinical- stage SMAC mimetic. We ~~have~~ also in- ~~licensed~~ - **license, and may in the future in- license,** certain ~~antibodies~~ **antibody binding domains** for our discovery **and clinical development** programs from third parties. Under these license agreements, we are able to research and initially develop discovery programs and are required to make certain annual payments. We also have the option to negotiate or enter into commercial license agreements with these third parties if we elect to continue development or commercialization of any product candidates incorporating the in- licensed antibodies. If we exercise our option to negotiate or enter into any commercial licenses with these third parties, we will likely be subject to various additional obligations, which may include obligations with respect to funding, development and commercialization activities, and payment obligations upon achievement of certain milestones and royalties on product sales. Our current license agreements impose, and any future license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If any of our licenses or future commercial licenses are terminated or breached, we may: ▪ lose our rights or options to research, develop or commercialize product candidates covered by the licensed technology; ▪ not be able to secure patent or trade secret protection for product candidates covered by the licensed technology; ▪ experience significant delays in the development or commercialization of product candidates covered by the licensed technology; ▪ not be able to obtain other licenses that may allow us to continue to progress the applicable programs on acceptable terms, if at all; or ▪ incur liability for damages. Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from or to third parties. If our licensors and future licensors fail to prosecute, maintain, enforce and defend patents we may license, or lose rights to licensed patents or patent applications, our license rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or product candidates that is the subject of such licensed rights could be materially adversely affected. 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, misappropriating or otherwise violating the licensor' s intellectual property rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products if infringement or misappropriation were found, those amounts could 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. In addition, the agreements under which we currently license intellectual property or technology from or to 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 impact on our business and ability to achieve profitability. 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 any affected product candidates, which could have a material adverse effect on our business and financial conditions. Our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged. Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and / or unenforceable. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable. With respect to challenges to the validity of our patents, for example, there might be 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 and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and / or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel. Our intellectual property rights will not necessarily provide us with competitive advantages. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: ▪ others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own, co- own, or have licensed; ▪ others may independently develop similar or alternative technologies without infringing our intellectual property rights; ▪ issued patents that we own, co- own, or have licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; ▪ we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited; ▪ our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ▪ we may fail to develop additional proprietary technologies that are patentable; ▪ the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and ▪ the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications . Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business. We may become involved in lawsuits to protect or enforce our patents and trade secrets, which could be expensive, time consuming and unsuccessful. Third parties may seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement, which may lead to challenges to the validity or enforceability of our patents. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Even after they have issued, our patents and any patents that we license may be challenged, narrowed, invalidated , or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us: ▪ we may initiate litigation or other proceedings against third parties to enforce our patent and trade secret rights; ▪ third parties may initiate litigation or other proceedings seeking to invalidate patents owned by, co- owned by, or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents co- owned by us, or licensed to us; ▪ third parties may initiate opposition, IPR or PGR proceedings challenging the validity or scope of our patent rights, requiring us and / or licensors to participate in such proceedings to defend the validity and scope of our patents; ▪ there may be a challenge or dispute regarding inventorship or ownership of patents or trade secrets currently identified as being owned by, co- owned, or licensed to us; or ▪ third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by, co- owned by us, or licensed to us , under the Biologics Price Competition and Innovation Act of 2009, requiring us to defend our patents, including by filing lawsuits alleging patent infringement. These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. Adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed or trade secrets not misappropriated by a third party' s activities, or that the scope of certain issued claims must be further limited.

An adverse outcome in a litigation or proceeding involving our own patents or trade secrets could limit our ability to assert our patents or trade secrets against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using , and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. 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 an adverse effect on the price of our common stock. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: ▪ others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents; ▪ others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents; ▪ we might not have been the first to make the inventions covered by patents or pending patent applications; ▪ we might not have been the first to file patent applications for these inventions; ▪ any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or ▪ we may not develop additional proprietary technologies that are patentable or that afford meaningful trade secret protection. 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 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, co-owned, and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not obtain protection under the Hatch- Waxman amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed. Depending upon the timing, duration and conditions of 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. 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. The Hatch- Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not receive an extension if we 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. 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 that product 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, possibly materially. 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. If we are unable to protect the confidentiality of our trade secrets and proprietary information, the value of our technology and products could be adversely affected. In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. ~~For example, we treat our proprietary computational technologies, including unpatented know- how and other proprietary information, as trade secrets.~~ Trade secrets and know- how can be difficult to protect. Trade secrets and know- how can also in some instances be independently derived or reverse- engineered by a third party. We maintain the confidentiality of trade secrets and proprietary information, in part by entering into confidentiality agreements with our employees, consultants, strategic partners and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual' s relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and even when we obtain these agreements, parties with whom we have these agreements may not comply with their terms. Any of the parties to these agreements may breach such agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. We may also become involved in inventorship disputes relating to inventions and patents developed by our employees or consultants under such agreements. To the extent that our employees, consultants or contractors use technology or know- how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual' s assignee. Such assignment or license may not be available on commercially reasonable terms or at all. 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. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition **,** and results of operations. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, or if we otherwise lose protection for our trade secrets or proprietary know- how, the value of this information may be greatly reduced and our business and competitive position could be harmed. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or other proprietary information of our employees' or consultants' former employers or their clients. We employ individuals who were previously or concurrently employed at research institutions and / or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. 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, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, trade secrets or other proprietary information could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such license may not be available on commercially reasonable terms or at all. A loss of key research personnel or their work product could limit our ability to commercialize, or prevent us from commercializing, our current or future technologies or product candidates, which could materially 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. Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and 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 or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees automatically when due, but we must notify the provider of any new patents or applications. Additionally, the USPTO and various foreign patent offices 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 rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. We may be subject to claims challenging the inventorship of our patents and other intellectual property. Although we are not currently experiencing any claims challenging the inventorship or ownership of our patents, we may in the future be subject to claims that former employees, strategic partners or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. 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. For example, the assignment of intellectual property rights may not be self- executing ~~or~~ **,** the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. 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. 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. Patent protection and patent prosecution for some of our product candidates may be dependent on, and the ability to assert patents and defend them against claims of invalidity may be maintained by, third parties. The prosecution of certain patent applications and the maintenance and enforcement of certain patents that relate to our product candidates are **and may be in the future** controlled by our licensors or licensees. Although we may, under such arrangements, have rights to consult with our strategic partners on actions taken as well as back- up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers. For example, under our collaboration agreement with Sanofi, in specified circumstances, Sanofi controls the prosecution and enforcement of certain of the patents and patent applications licensed to it. If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or found to be enforceable in our patents or in third- party patents. The United States has enacted and is currently implementing wide- ranging patent reform legislation. Further, recent U. S. Supreme Court and Court of Appeals for the Federal Circuit rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty ~~with regard~~ **regarding** ~~to~~ our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity, scope **,** and value of patents ~~,~~ once obtained. For our U. S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy- Smith America Invents Act, also known as the America Invents Act (AIA), was signed into law. The AIA includes **several** ~~a number of~~ significant changes to U. S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties disclosing or claiming the same invention. A third party that has filed ~~,~~ or does file a patent application in the USPTO after March 16, 2013 but before us, could be awarded a patent covering a given invention, even if we had made the invention before it was made by the third party. This requires us to be cognizant going forward of the time from invention to filing of a patent application. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to file third party submissions of prior art to the USPTO during patent prosecution and to challenge any issued patent in the USPTO (e. g., via post- grant reviews or inter partes reviews). This applies to all ~~of~~ our U. S. patents, even those issued before March 16, 2013. ~~Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.~~ Depending on decisions by the U. S. Congress, the U. S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future. Additionally, ~~by~~ as **of** ~~early as~~ June 1, 2023, existing European patents, and European patent applications, upon grant of a patent, ~~will~~ have the option of becoming a Unitary Patent, which will be subject to the jurisdiction of the ~~Unitary~~ **Unified** Patent Court (UPC). During a sunrise period **that** ~~, set to begin~~ **began on** March 1, 2023, European patent owners ~~will~~ have the ability to opt out of being subjected to the jurisdiction of the UPC. The option of a Unitary Patent will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Recent United States Supreme Court cases have narrowed the scope of what is considered patentable subject matter, for example, in the areas of software and diagnostic methods involving the association between treatment outcome and biomarkers. This could impact our ability to patent certain aspects of our technology in the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing **,** and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status, and patenting of medical uses of a claimed drug are prohibited. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own, co- own, or license. We will need to obtain FDA approval for any proposed product candidate names, and any failure or delay associated with such approval may adversely affect our business. Any proprietary name or trademark we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product candidate names, including an evaluation of the potential for confusion with other product names and potential pharmacy dispensing errors. The FDA may also object to a product name if it believes the name inappropriately implies certain medical claims or contributes to an overstatement of efficacy. If the FDA objects to any product candidate names we propose, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we ~~would~~ **could** lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates. Risks Related to Ownership of Our Securities The market price of our common stock may be volatile, which could result in substantial losses for our securityholders. The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include: ▪ results and timing of our preclinical studies and clinical trials and studies and trials of our competitors' products; ▪ failure or discontinuation of any of our development programs; ▪ issues in manufacturing our product candidates or future approved products; ▪ regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products; ▪ competition from existing products or new products that may emerge; ▪ actual or anticipated changes in our growth rate relative to our competitors; ▪ developments or disputes concerning patents or other proprietary rights; ▪ introduction of technological innovations or new commercial products by us or our competitors; ▪ commencement or termination of collaborations for our programs; for instance, without limitation, our collaboration with Sanofi; ▪ announcements by us, our strategic partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments; ▪ actual or anticipated changes in estimates or recommendations by securities analysts, if any cover our common stock; ▪ fluctuations in the valuation of companies perceived by investors to be comparable to us; ▪ public concern over our product candidates or any future approved products; ▪ litigation; ▪ future sales of our common stock by us, our insiders or our other stockholders; ▪ share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; ▪ additions or departures of key personnel; ▪ changes in the structure of health care payment systems in the United States or overseas; ▪ failure of any of our product candidates, if approved, to achieve commercial success; ▪ economic and other external factors or other disasters, crises or public health emergencies, such as the COVID- 19 pandemic; ▪ period- to- period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements; ▪ announcements or expectations of additional financing efforts; ▪ general market conditions and market conditions for biotechnology stocks; ▪ overall fluctuations in U. S. equity markets; and ▪ other factors that may be unanticipated or out of our control **.** The stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stock often does not relate to the operating performance of the companies presented by the stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the ~~company that issued~~ **issuer of** the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business. An active trading market for our common stock may not **continue to** be **developed or** sustained ~~. Prior to the closing of our IPO in September 2019~~ , ~~there~~ **and** ~~was~~ - **as** ~~no public market~~ **a result it may be difficult** for **you to sell your shares of** our common stock. Although our common stock is listed on the Nasdaq Global Select Market (Nasdaq), the market for our shares has demonstrated varying levels of trading activity **and** ~~. Furthermore,~~ an active ~~market~~ trading market for our common stock may not be sustained ~~in the future~~ . The lack of an active trading market for our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the market value of their shares, may impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. We are controlled by Topsøe Holding A / S and a concentrated group of stockholders, whose interests in our business may conflict with yours. As of December 31, ~~2022~~ **2023** , Topsøe Holding A / S, together with other holders of 5 % or more of our outstanding capital stock and their respective affiliates, beneficially owned ~~over 70 %~~ **a majority of the shares** of our outstanding capital stock. Accordingly, our principal stockholders will be able to control most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, including mergers and sales of all or substantially all of our assets. The interests of these principal stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders. For example, our concentration of ownership could have the effect of delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could cause the market price of our common stock to decline or prevent our stockholders from realizing a premium over the market price for their shares of our common stock. In addition, pursuant to nominating agreements entered into between us and each of (i) Topsøe Holding A / S, (ii) Baker Brothers Life Sciences L. P. and 667, L. P. (together, Baker Brothers) and (iii) Redmile Biopharma Investments II, L. P., RAF, L. P. and Redmile Strategic Master Fund, LP (together, Redmile), for up to 12 years following the completion of our IPO, so long as Topsøe Holding A / S, Baker Brothers and Redmile, together with their respective affiliates, each beneficially own certain specified amounts of our capital stock, we will have the obligation to support the nomination of, and to cause our board of directors to include in the slate of nominees recommended to our stockholders for election, (i) two individuals designated by Topsøe Holding A / S, (ii) one individual designated by Baker Brothers and (iii) one individual designated by Redmile, subject to certain customary conditions and exceptions. Each of Topsøe Holding A / S, Baker Brothers and Redmile, and their respective affiliates, may therefore have influence over management and control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions. The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions. The dual class structure of our common stock may also limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non- voting common stock are not entitled to any votes. Nonetheless, each share of our non- voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation as currently in effect. Consequently, if holders of our non- voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non- voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10 % of our common stock and non- voting common stock, but 10 % or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non- voting common stock pursuant to Section 16 (a) of the Exchange Act, and may not be subject to the short- swing profit provisions of Section 16 (b) of the Exchange Act. Sales of substantial amounts of our common stock in the public markets, or the perception that such sales could occur, could cause the market price of our common stock to decline significantly, even if our business is doing well. 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 amount of our common stock in the public market, the market price of our common stock could decline significantly. We currently have on file with the SEC an effective shelf registration statement on Form S- 3, which allows us to offer debt securities, preferred stock, common stock, non- voting common stock and certain other securities from time to time. If in the future we issue shares of common stock or securities convertible into common stock, our stockholders would experience dilution and, as a result, the market price of our common stock may decline. We cannot predict the effect that future sales of our securities would have on the market price of our common stock. Additionally, our ~~securityholders~~ **security holders** may be further diluted by the exercise of the pre- funded warrants issued in December 2020 or by **any issuance of our voting common stock issuable upon the conversion of issued and outstanding shares of our non- voting common stock.** Certain holders of our common stock (including common stock issuable upon conversion of our non- voting common stock) have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. In addition, we filed a registration statement on Form S- 8 to register shares of our common stock reserved for future issuance under our equity compensation plans **;** ~~. As a result,~~ shares registered under this ~~registration statement~~ **Form S- 8** will be available for sale in the public market subject to the satisfaction of applicable vesting arrangements and the exercise of such options and, in the case of our affiliates, the restrictions of Rule 144. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline **.** Raising additional capital may cause dilution to our stockholders,restrict our operations or require us to relinquish substantial rights.We may from time to time raise additional capital through the sale of equity or convertible securities,including pursuant to an effective shelf registration statement.If we issue additional shares of common stock at a discount from the current trading price of our common stock,our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount.In addition,as opportunities present themselves,we may enter into financing or similar arrangements in the future,including the issuance of debt securities,preferred stock,common stock,or non- voting common stock ~~.On April 1,2022,pursuant to our registration statement on Form S- 3 (File No.333- 258644),we completed a public offering of 8,695,653 shares of our non- voting common stock,with an option for the underwriters to purchase 1,304,347 shares of our voting common stock,which was exercised in full,for aggregate gross proceeds of $ 230.0 million.After deducting underwriting discounts and commissions and offering costs paid or payable by us of approximately $ 12.0 million,the aggregate net proceeds from this public offering were approximately $ 218.0 million~~ .If in the future we issue shares of common stock or securities convertible into common stock,our stockholders would experience dilution and,as a result,the market price of our common stock may decline.We cannot predict the effect that future sales of our common stock would have on the market price of our common stock.Additionally,our stockholders may be further diluted by the exercise of the pre- funded warrants issued in December 2020 **in connection with a financing** (see Note 8 **– Stockholders' Equity** to our consolidated financial statements included elsewhere in this Annual Report on Form 10- K for additional information) and any issuance of our voting common stock issuable upon the conversion of shares of non- voting common stock currently outstanding.Further,if we raise additional capital through the sale of equity or convertible securities,the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a stockholder.Debt financing,if available at all,may involve fixed payment obligations or agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt,making capital expenditures,or declaring dividends.If we raise additional funds through partnerships,collaborations,strategic alliances,or licensing arrangements with third parties,we may have to relinquish valuable rights to our technologies,product candidates,or future revenue streams,or grant licenses on **terms that are not favorable to us.We cannot assure you that we will be able to obtain additional funding if and when necessary.If we are unable to obtain adequate financing on a timely basis,we could be required to delay,scale back or eliminate one or more of our clinical or discovery programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.In addition,we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans** . If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline. The trading market for our common stock depends on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or change their opinion of our common stock, our share price would likely decline. In addition, if one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. We have identified deficiencies in the past which we have taken steps to address. However, our efforts to remediate previous deficiencies may not be effective or prevent any future deficiency in our internal control over financial reporting. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. ~~During the year ended December 31, 2020, we began using a new enterprise resource planning (ERP) system for financial reporting. As a result, we updated our internal controls to accommodate changes to our business processes and accounting procedures.~~ In connection with our ongoing ~~evaluation~~ **evaluations** of ~~our~~ internal controls over financial reporting, we **have made, and** may **continue to** make ~~further~~ upgrades to our finance and accounting systems. If we are unable to accomplish these ~~objectives~~ **upgrades** in a timely and effective manner, our ability to comply with the financial reporting requirements and other rules that apply to reporting companies could be adversely impacted. Any failure to maintain effective internal control over financial reporting could have a material adverse effect on our business, financial condition and results of operations and the trading price of our common stock. As a public company, we are required to disclose material changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Additionally, we are required to include a formal management assessment of the effectiveness of our internal control over financial reporting in our periodic reports, and once we cease to be an emerging growth company, unless another exemption is available, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, for as long as we are an " emerging growth company " under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. To achieve compliance with Section 404 within the prescribed period, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and maintain a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and continue to implement a continuous reporting and improvement process for internal control over financial reporting. An independent assessment of the effectiveness of our internal controls could detect problems that our management' s assessment might not. In addition, our independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting as of December 31, **2023,** 2022 ~~,~~ **or** 2021 ~~or 2020~~ in accordance with the provisions of the Sarbanes- Oxley Act. Had our independent registered public accounting firm performed such an evaluation, control deficiencies may have been identified by management or our independent registered public accounting firm, and those control deficiencies could have also represented one or more material weaknesses. Undetected material weaknesses in our internal controls could lead to consolidated financial statement restatements and require us to incur the expense of remediation. We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time to corporate governance standards. As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an " emerging growth company. " Our management and other personnel have devoted and will continue to devote a substantial amount of time and incur substantial expense in connection with compliance initiatives. For example, in anticipation of becoming a public company, we adopted additional internal controls and disclosure controls and procedures, retained a transfer agent and adopted an insider trading policy. As a public company, we bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws. In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes- Oxley Act and the related rules and regulations implemented by the SEC and Nasdaq, have and will continue to increase legal and financial compliance costs and make some compliance activities more time consuming. We cannot predict or estimate the amount of additional costs we may incur to respond to these requirements or the timing of such costs. We have invested and will continue to invest in resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management' s time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers. Under the corporate governance standards of Nasdaq, a majority of our board of directors and each member of our audit committee must be an independent director. We may encounter difficulty in attracting qualified persons to serve on our board of directors and the audit committee, and our board of directors and management may be required to divert significant time and attention and resources away from our business to identify qualified directors. If we fail to attract and retain the required number of independent directors, we may be subject to the delisting of our common stock from Nasdaq. We are an emerging growth company and a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved ~~. We will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year in which we have more than $ 1. 07 billion in annual gross revenue, the date we qualify as a " large accelerated filer, " with the market value of our common stock held by non- affiliates exceeding $ 700 million as of June 30, the issuance by us of more than $ 1. 0 billion of non- convertible debt over a three- year period, and the last day of the fiscal year ending after the fifth anniversary of our IPO, or December 31, 2024~~. Investors could find our common stock less attractive if we choose to rely on these exemptions. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to use this extended transition period until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates **. We will cease to be an emerging growth company on December 31, 2024**. We are also currently a " smaller reporting company " as defined in the Exchange Act. Smaller reporting companies may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including, among others, not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Additionally, as a smaller reporting company, we are only required to provide two years of audited financial statements in our SEC reports. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common stock held by non- affiliates equals or exceeds $ 250 million as of the prior June 30, or (2) our annual revenues equal or exceed $ 100 million during such completed fiscal year and the market value of our common stock held by non- affiliates equals or exceeds $ 700 million as of the prior June 30. If we take advantage of some or all of the reduced disclosure requirements available to emerging growth companies or smaller reporting companies, investors may find our common stock less attractive, which may result in a less active trading market for our common stock and greater stock price volatility. We have never paid and do not anticipate paying cash dividends on our common stock, and accordingly, stockholders must rely on share appreciation for any return on their investment. We have never paid any dividends on our capital stock. We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses and do not anticipate that we will declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, capital appreciation, if any, **will be the sole source** of **gain on any investment in** our common stock ~~will be your sole source of gain on your investment~~ for the foreseeable future. Investors seeking cash dividends should not invest in our common stock. Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents: ▪ establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three- year terms; ▪ provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; ▪ provide that our directors may only be removed for cause; ▪ eliminate cumulative voting in the election of directors; ▪ authorize our board of directors to issue shares of convertible preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval; ▪ provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship; ▪ permit stockholders to only take actions at a duly called annual or special meeting and not by written consent; ▪ prohibit stockholders from calling a special meeting of stockholders; ▪ require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings; ▪

authorize our board of directors, by a majority vote, to amend the bylaws; and ▪ require the affirmative vote of at least 66 2 / 3 % or more of the outstanding shares of common stock to amend many of the provisions described above. In addition, Section 203 of the General Corporation Law of the State of Delaware ( **the** DGCL) prohibits a publicly- held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15 % of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for certain claims as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court): ▪ any derivative action or proceeding ~~under Delaware statutory or common law~~ brought on our behalf; ▪ any action asserting a claim of breach of fiduciary duty owed by any of our directors **, stockholders** , officers or other employees to us or our stockholders; ▪ any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and ▪ any action asserting a claim against us that is governed by the internal- affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Exchange Act or any **successor thereto** ~~other claim for which the federal courts have exclusive jurisdiction~~ . Our amended and restated bylaws further provide that the federal district courts of the United States will be the **sole and** exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act **against any person in connection with any offering of our securities** . These exclusive- 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 our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive- forum provision in our amended and restated bylaws to be inapplicable or unenforceable in any action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.