Risk Factors Comparison 2024-03-27 to 2023-03-29 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

~~required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our drug candidates, our expenses could increase.~~ Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or even continue our operations. A decline in the value of our company could also result in significant harm to our financial position and adversely affect our stock price. We will need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed, we may not be able to continue as a going concern and could be forced to delay, reduce or eliminate our drug development programs or potential commercialization efforts. We believe that our **existing** cash and cash equivalents ~~as of the date of this report~~ will enable us to fund our operating expenses and capital expenditure requirements through the fourth quarter of 2024. However, we will need to obtain substantial additional funding in connection with our continuing operations. Our future capital requirements will depend on many factors, including: ● the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our drug candidates; ● the number and development requirements of other drug candidates that we may pursue; ● the costs, timing and outcome of regulatory review of our drug candidates; ● the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive marketing approval; ● the revenue, if any, received from commercial sales of our drug candidates for which we receive marketing approval; ● the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims; and ● the extent to which we acquire or in-license other drug candidates and technologies. **Our management must periodically evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. Based on our current cash position, our ongoing significant operating losses and the fact that we do not have any committed sources of revenue or cash flows other than potential payments from our license and collaboration agreements, management believes that, given our current cash position, there is substantial doubt about our ability to continue as a going concern beyond the date that is one year from the date that the financial statements included in this Annual Report were issued.** Identifying potential drug candidates and conducting preclinical testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we or any current or future collaborators may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our drug candidates, if approved, may not achieve commercial success ~~. Our commercial revenue, if any, will be derived from the sale of drugs that we do not expect to be commercially available for several years, if at all~~ . Accordingly, our ability to fund our operations is dependent upon management' s plans, which include raising additional capital in the near term primarily through a combination of equity and debt financings, collaborations and strategic alliances. There can be no assurances that new financings or other transactions will be available to us on commercially acceptable terms, or at all. ~~Currently, we are not actively developing GMI- 1359 or GMI- 1687~~ **Our ability to raise additional capital may also be adversely impacted by global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide** . If we are unable to raise capital to fund our operations when needed or on attractive terms, we could be forced to delay, reduce the scope of or eliminate our research and development programs or any future commercialization efforts, which would have a material adverse effect on our business, financial condition, results of operations and ability to operate as a going concern. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our drug candidates. Until such time, if ever, as we can generate substantial revenue from the sale of our drugs, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and development agreements. We do not currently have any committed external source of funds other than possible milestone payments and possible royalties under our license agreement with Apollomics. To the extent that we raise additional capital through the sale of equity or ~~convertible~~ **26convertible** debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. ~~26If~~ **If** we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our research programs or drug candidates or grant licenses on terms that may not be favorable to us or that may be at less than the full potential value of such rights. If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to third parties to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. Our ~~operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We commenced operations in 2003, and our operations to date have been largely focused on raising capital, developing our expertise in carbohydrate chemistry and knowledge of carbohydrate biology, identifying potential drug candidates, undertaking preclinical studies and conducting clinical trials. We have not yet demonstrated our ability to successfully complete later stage clinical trials, obtain regulatory approvals, manufacture a commercial scale drug, or arrange for a third party to do so on our behalf, or~~

~~conduct sales and marketing activities necessary for successful commercialization. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performanceOur~~ ability to use net operating losses to offset future taxable income may be subject to limitations. As of December 31, ~~2022~~ **2023** , we had federal and state net operating loss carryforwards of $ ~~300~~ **322** . ~~8~~ **5** million, research and development tax credit carryforwards of $ 10. ~~6~~ **9** million and $ ~~40~~ **42** . ~~6~~ **3** million of orphan drug tax credit carryforwards. The federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2026, the research and development tax credits in ~~2023~~ **2024** and the orphan drug tax credit in 2033. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under federal income tax laws, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. We could experience ownership changes in the future that would limit our ability to use our net operating loss carryforwards. Risks Related to the Discovery and Development of Our Drug CandidatesOur research and development is focused on discovering and developing novel glycomimetic drugs, and we are taking an innovative approach to discovering and developing drugs, which may never lead to marketable drugs. A key element of our strategy is to use and expand our platform to build a pipeline of novel glycomimetic drug candidates and progress these drug candidates through clinical development for the treatment of a variety of diseases. The discovery of therapeutic drugs based on molecules that mimic the structure of carbohydrates is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop drug candidates are relatively new. The scientific evidence to support the feasibility of developing drug candidates based on these discoveries is both preliminary and limited. Although our research and development efforts to date have resulted in a pipeline of glycomimetic drug candidates, we may not be able to develop drug candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential drug 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 drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize drug candidates based upon our glycomimetics platform, we will not be able ~~27to~~ **to** obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price. We have only one drug candidate in a late- stage clinical trial. All of our other drug candidates are in **earlier stages of clinical trials or in** preclinical development. If we or our collaborators are unable to commercialize our drug candidates or experience significant delays in doing so, our business will be materially harmed. Uproleselan is our only drug candidate that is in a Phase 2 or Phase 3 clinical trial. Our other drug candidates are ~~still~~ **in earlier stages of clinical trials or** in preclinical development. We have not completed the development of any drug candidates, we currently generate no revenue from the sale of any drugs and we may never be able to develop a marketable drug. **As a company, we have no experience in submitting and obtaining FDA approval for an NDA and, even if our uproleselan trials are successful, FDA may disagree with our interpretation of the data and our NDA may receive either a refusal to file letter or complete response letter.** We have invested substantially all of our efforts and financial resources in the development of our glycomimetics platform, the identification of potential drug candidates ~~using~~ **27using** that platform and the development of our drug candidates. Our ability to generate revenue from our other drug candidates, which we do not expect to occur for many years, if ever, will depend heavily on their successful development and eventual commercialization. The success of those drug candidates will depend on several factors, including: ● successful completion of preclinical studies and clinical trials; ● receipt of marketing approvals from applicable regulatory authorities; ● obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates; ● making arrangements with third- party manufacturers for, or establishing, commercial manufacturing capabilities; ● launching commercial sales of the drugs, if and when approved, whether alone or in collaboration with others; ● acceptance of the drugs, if and when approved, by patients, the medical community and third- party payors; ● effectively competing with other therapies; ● obtaining and maintaining healthcare coverage and adequate reimbursement; ● protecting our rights in our intellectual property portfolio; and ● maintaining a continued acceptable safety profile of the drugs following approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would materially harm our business. Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates. The risk of failure of our drug candidates is high. It is impossible to predict when or if any of our drug candidates will prove safe or effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we or a collaborator must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of development. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In addition, changes in patient treatment options over time may make the relevance of historical control data for a given indication less relevant to the drug candidate

being studied, which could impact the success of the trial or, even if successful, the desirability of a successful drug candidate versus other available treatment options. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. ~~28We~~ **We** or our current or future collaborators may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our or their ability to receive marketing approval or commercialize our drug candidates, including: ● regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; ● we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; ● clinical trials of our drug candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; **28** ● the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate; ● our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ● regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; ● the cost of clinical trials of our drug candidates may be greater than we anticipate; ● the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and ● our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials. If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these clinical trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: ● be delayed in obtaining marketing approval for our drug candidates; ● not obtain marketing approval at all; ● obtain approval for indications or patient populations that are not as broad as intended or desired; ● obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; ● be subject to additional post- marketing testing requirements; or ● have the drug removed from the market after obtaining marketing approval. Our drug development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do, and thereby impair our ability to successfully commercialize our drug candidates. If serious adverse or unacceptable side effects are identified during the development of our drug candidates,we may need to abandon or limit the development of some of our drug candidates.If our drug candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected,we may need to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent,less severe or more acceptable from a risk- benefit perspective.Many drug candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented their further development.We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.Because we have limited financial and management resources,we focus on a limited number of research programs and drug candidates.As a result,we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. ~~29Our -- are unexpected,we may need to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent,less severe or more acceptable from a risk- benefit perspective.Many drug candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented their further development.We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.Because we have limited financial and management resources,we focus on a limited number of research programs and drug candidates.As a result,we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential.~~ Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities.Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable drugs.If we do not accurately evaluate the commercial potential or target market for a particular drug candidate,we may relinquish valuable rights to that drug candidate through collaboration,licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. ~~Risks~~ **29Risks** Related to Our Dependence on Third PartiesOur success depends in part on current and future collaborations.If we are unable to maintain any of these collaborations,or if these collaborations are not successful,our business could be adversely affected.We have limited capabilities for drug development and do not yet have any capabilities for sales,marketing or distribution.We cannot assure you that our current or future collaborators will develop our drug candidates in a timely manner,or at all,or,if regulatory approval for a drug candidate is achieved,that such collaborator will successfully commercialize the candidate.Any collaborations we might enter into may pose a number of risks,including:● collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;● collaborators may not perform their obligations as expected;● collaborators may not pursue the commercialization of any drug candidates that achieve regulatory approval or may elect not to pursue,continue or renew development or commercialization of drug candidates based on clinical trial results,changes in such collaborators' strategic focus or available funding or external

factors,such as an acquisition,that divert resources or create competing priorities;● collaborators may delay clinical trials,provide insufficient funding for a clinical trial program,stop a clinical trial or abandon a drug candidate,repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing; ~~30~~ ● collaborators could experience delays in initiating or conducting clinical trials for any number of reasons;● collaborators could independently develop,or develop with third parties,drugs that compete directly or indirectly with our drugs or drug candidates if such collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;● drug candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own drug candidates or drugs,which may cause such collaborators to cease to devote resources to the commercialization of our drug candidates;● a collaborator with marketing and distribution rights to one or more of our drug candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such drug or drugs;● disagreements with collaborators,including disagreements over proprietary rights,contract interpretation or the preferred course of development,might cause delays or termination of the research,development or commercialization of drug candidates,might lead to additional responsibilities for us with respect to drug candidates or might result in litigation or arbitration,any of which would be time consuming and expensive;● collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;● collaborators may infringe the intellectual property rights of third parties,which may expose us to litigation and potential liability;and ● collaborations may be terminated for the convenience of the collaborator and,if terminated,we could be required to raise additional capital to pursue further development or commercialization of the applicable drug candidates.We are seeking licensing partners for development of GMI- 1359.If any collaborations we might enter into do not result in the successful development and commercialization of drugs,or if one of our collaborators terminates its agreement with us,we may not receive any future research funding or milestone or royalty payments under the collaboration.For example,in ~~February~~ 2020, **our former collaborator** Pfizer terminated its license agreement with us for the ~~worldwide~~ **30worldwide** development and commercialization of our prior drug candidate rivipansel,thereby eliminating our right to receive any future development or commercialization milestones or royalty payments for sales of that drug candidate.In addition,even if we are eligible to receive any such payments from a collaborator,they could be substantially delayed.If we do not receive the funding we expect under these agreements,the development of our drug candidates could be delayed and we may need additional resources to develop our drug candidates.All of the risks relating to drug development,regulatory approval and commercialization described in this report also apply to the activities of our collaborators.If a current or future collaborator of ours is involved in a business combination,the collaborator might deemphasize or terminate development or commercialization of any drug candidate licensed to it by us.If one of our collaborators terminates its agreement with us,we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.We may in the future determine to collaborate with pharmaceutical and biotechnology companies for their development and potential commercialization of our drug candidates.We face significant competition in seeking appropriate collaborators.Our ability to reach a definitive agreement for a collaboration will depend,among other things,upon our assessment of a collaborator' s resources and expertise,the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors.If we are unable to reach agreements with suitable collaborators on a timely basis,on acceptable terms,or at all,we may have to curtail the development of a drug candidate,reduce or delay its development or 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 collaborations and do not have sufficient funds or expertise to undertake the necessary development and ~~31commercialization~~ -- **commercialization** activities,we may not be able to further develop our drug candidates or bring them to market,which would impair our business prospects.We expect to rely on third parties to conduct our future clinical trials for drug candidates,and those third parties may not perform satisfactorily,including failing to meet deadlines for the completion of such trials.We have engaged a third- party contract research organization,or CRO,to conduct our ongoing and planned clinical trials for uproleselan and expect to engage CROs with respect to any of our other drug candidates that may progress to clinical development.We expect to continue to rely on third parties,such as CROs,clinical data management organizations,medical institutions and clinical investigators,to conduct those clinical trials.Agreements with such third parties might terminate for a variety of reasons,including a failure to perform by the third parties.If we need to enter into alternative arrangements,that would delay our drug development activities.Our reliance on these third parties for research and development activities will reduce our control over these activities,but will not relieve us of our responsibilities.For example,we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial.Moreover,the FDA requires us to comply with standards,commonly referred to as good clinical practices,or GCPs,for conducting,recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights,integrity and confidentiality of trial participants are protected.We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database,ClinicalTrials.gov,within specified timeframes.Failure to do so can result in fines,adverse publicity and significant civil and criminal sanctions.Furthermore,these third parties may also have relationships with other entities,some of which may be our competitors.If these third parties do not successfully carry out their contractual duties,meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols,we will not be able to obtain,or may be delayed in obtaining,marketing approvals for our drug candidates and will not be able to,or may be delayed in our efforts to,successfully commercialize our drug candidates.We also expect to rely on other third parties to store

and distribute drug supplies for our clinical trials.Any performance failure on the part of our distributors could delay clinical development or marketing approval of our drug candidates or commercialization of our drugs,producing additional losses and depriving us of potential revenue. ~~We~~ **31We** contract with third parties for the manufacturing of our drug candidates for preclinical and clinical testing and expect to continue to do so for commercialization.This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs,or such quantities at an acceptable cost,which could delay,prevent or impair our development or commercialization efforts.We do not have any manufacturing facilities or personnel.We rely,and expect to continue to rely,on third parties for the manufacturing of our drug candidates for preclinical and clinical testing,as well as for commercial manufacture if any of our drug candidates receives marketing approval. ~~Disruption to our supply arrangements may arise from unforeseeable events that impact such third parties,including the COVID- 19 pandemic.~~ Our reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs,or such quantities at an acceptable cost or quality,which could delay,prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.We also expect to rely on third- party manufacturers or third- party collaborators for the manufacturing of commercial supply of any other drug candidates for which we or our collaborators obtain marketing approval. **For example,in January 2024 we entered into an agreement with Patheon Manufacturing Services LLC,or Patheon,for manufacture and supply of uproleselan for commercial sale should we receive marketing approval from the FDA.Pursuant to the agreement,Patheon will manufacture commercial quantities of injectable uproleselan from active pharmaceutical ingredient we supply under a separate agreement for the manufacture of drug substance with another third- party manufacturer,Carbogen Amcis AG.** We may be unable to establish any agreements with third- party manufacturers or to do so on acceptable terms.Even if we are able to establish agreements with third- party manufacturers,reliance on third- party manufacturers entails additional risks,including:● reliance on the third party for regulatory compliance and quality assurance;● the possible breach of the manufacturing agreement by the third party;● the possible misappropriation of our proprietary information,including our trade secrets and know- how;and ● the possible termination or non- renewal of the agreement by the third party at a time that is costly or inconvenient for us. ~~32Third --~~ **Third** - party manufacturers may not be able to comply with current good manufacturing practices,or cGMP,regulations or similar regulatory requirements outside the United States.Our failure,or the failure of our third- party manufacturers,to comply with applicable regulations could result in sanctions being imposed on us,including clinical holds,fines,injunctions,civil penalties,delays,suspension or withdrawal of approvals,license revocation,seizures or recalls of drug candidates or drugs,operating restrictions and criminal prosecutions,any of which could significantly and adversely affect supplies of our drugs.In addition,in the event that any of our third- party manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality,timing or otherwise,or if our supply of components or other materials becomes limited or interrupted for other reasons,we may be forced to manufacture the materials ourselves,for which we currently do not have the capabilities or resources,or enter into an agreement with another third party,which we may not be able to do on commercially reasonable terms,if at all.We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance.If our current contract manufacturers cannot perform as agreed,we may be required to replace such manufacturers and we may incur added costs and delays in identifying and qualifying any such replacement.Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements.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 our drug candidates in a timely manner or within budget.Our current and anticipated future dependence upon others for the manufacturing of our drug candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis. ~~We~~ **32We** ,or our third- party manufacturers,may be unable to successfully scale- up manufacturing of our drug candidates in sufficient quality and quantity,which would delay or prevent us from conducting our ongoing and planned clinical trials and developing our drug candidates.In order to conduct our ongoing and planned clinical trials of our drug candidates,we will need to manufacture them in large quantities.We,or our manufacturing partners,may be unable to **successfully increase the manufacturing capacity for any of our drug candidates in a timely or cost- effective manner,or at all.In addition,quality issues may arise during scale- up activities.If we or our manufacturing partners are unable to successfully scale up the manufacture of our drug candidates in sufficient quality and quantity,the development,testing and clinical trials of that drug candidate may be delayed or become infeasible,and marketing approval or commercial launch of any resulting drug may be delayed or not obtained,which could significantly harm our business.Our** business could be adversely affected by the effects of health epidemics or pandemics in regions where we or third parties on whom we rely have significant manufacturing facilities, clinical trial sites or other business operations. Our business could be adversely affected by health epidemics or pandemics in regions where we have concentrations of clinical trial sites or other business operations ~~,~~ and could cause significant disruption in the operations of third- party collaborators, manufacturers and CROs upon whom we rely. Quarantines, shelter- in- place, stay- at- home, executive and similar government orders — or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur — could impact personnel at third- party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. For example, any manufacturing supply interruption of uproleselan, which is currently manufactured at facilities in Switzerland and China, could adversely affect our ability to conduct ongoing and future clinical trials of uproleselan. If serious adverse or unacceptable side effects..... which could significantly harm our business. Risks Related to the Commercialization of Our Drug CandidatesEven if any of our drug candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If any of our drug candidates receives marketing approval, it may nonetheless fail

to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from drug sales and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including: ● the efficacy and potential advantages compared to alternative treatments; ● our ability to offer our drugs for sale at competitive prices; ● the convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the strength of marketing and distribution support; ● the availability of third- party coverage and adequate reimbursement; ~~33~~ ● the prevalence and severity of any side effects; and ● any restrictions on the use of our drugs together with other medications. ~~If~~ **33If** we are unable to establish sales, marketing and distribution capabilities for our drug candidates, we may not be successful in commercializing those drug candidates if and when they are approved. We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical drugs. To achieve commercial success for any drug candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization to market or co- promote such drugs. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our drugs on our own include: ● our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to obtain access to physicians or ~~persuade~~ **our failure to educate** adequate numbers of physicians ~~to prescribe~~ **on the benefits of** any future drugs; ● the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more products; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we are unable to establish our own sales, marketing and distribution capabilities and **therefore** enter into arrangements with third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we were to sell, market and distribute any drugs that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our drug candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drugs effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do. The development and commercialization of new drugs is highly competitive. We face competition with respect to our current drug candidates, and we will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Should any competitors' drug candidates receive regulatory or marketing approval prior to ours, they may establish a strong market position and ~~be difficult to displace or~~ diminish the need for our drug candidates. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their safety, efficacy, convenience, price, the level of generic competition and the availability of coverage and reimbursement from government and other third- party payors. As described above under " Business — Competition, " we expect that our drug candidates will compete with approved therapies and those currently in development by other companies. To the extent that competitive drugs or drug candidates developed by others are successful in treating our target indications, it could reduce the market opportunity for our drug candidates. Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors ~~34also~~ -- **also** compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. ~~Our~~ **34Our** commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, because we have no patents with respect to our glycomimetics platform, our competitors may use our methods, or acquire similar expertise, in order to develop glycomimetic drug candidates and progress these drug candidates through clinical development and commercialization, which could impair our ability to successfully commercialize our drug candidates or otherwise limit our commercial opportunities. Even if we or our collaborators are able to commercialize any of our drug candidates, the drugs may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies. Our and our collaborators' ability to commercialize any of our drug candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these drugs and related treatments will be available from government payor programs at the federal and state levels authorities, including Medicare and Medicaid, private health insurers, managed care plans and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in

the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. Coverage and reimbursement may not be available for any drug that we or our collaborators commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, any drug candidate for which we or our collaborators obtain marketing approval. Obtaining and maintaining adequate reimbursement for our drugs may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we or our collaborators may not be able to successfully commercialize any drug candidates for which marketing approval is obtained. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, one payor' s determination to provide coverage for a drug does not assure that other payors will also provide coverage for the drug. Our or our collaborators' inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved drugs that we develop could adversely affect our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or 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 or our collaborators might obtain marketing ~~35approval --~~ **approval** for a drug in a particular country, but then be subject to price regulations that delay commercial launch of the drug, possibly for lengthy time periods, and negatively impact our ability to generate revenue from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval. ~~There~~ **35There** can be no assurance that our drug candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost- effective by third- party payors, that coverage or an adequate level of reimbursement will be available or that third- party payors' reimbursement policies will not adversely affect our ability to sell our drug candidates profitably if they are approved for sale. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any drugs that we may develop. We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials, and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our drug candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any drug candidates or drugs that we may develop; ● injury to our reputation and significant negative media attention; ● withdrawal of clinical trial participants; ● significant costs to defend the related litigation; ● substantial monetary awards paid to trial participants or patients; ● loss of revenue; ● reduced resources of our management to pursue our business strategy; and ● the inability to commercialize any drugs that we may develop. We carry clinical trial insurance coverage in an amount that we believe is sufficient in relation to our clinical trials being conducted in the United States and in foreign countries where we have or plan to have sites as part of our clinical trials for uproleselan. The use of our drug candidates in clinical trials may result in liability claims for which our current insurance would not be adequate to cover all liabilities that we may incur. In addition, we may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our drug candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Risks Related to Our Intellectual PropertyIf we are unable to obtain and maintain patent protection for our drug candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our drug candidates may be impaired. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our drug candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our drug candidates. The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and

factual questions and has in recent years been the subject of much litigation. In addition, the laws of ~~36foreign~~ **foreign** countries may not protect our rights to the same extent as the laws of the United States, or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent ~~applications~~ **36applications** in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive drug candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The **USPTO** ~~U. S. Patent and Trademark Office~~ recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act 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 a material adverse effect on our business and financial condition. Moreover, we may be subject to a third- party preissuance submission of prior art to the U. S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our drug candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third- party patent rights. 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 drug candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative drug candidates in a non- infringing manner. In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical drug candidates, or limit the duration of the patent protection of our drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. 37We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent, rights that are important or necessary to the development of our drug candidates. It may be necessary for us to use patented or proprietary technology of third parties to commercialize our drug candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our drug candidates without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates, including interference or derivation proceedings before the **USPTO** ~~U. S. Patent and Trademark Office~~. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our drug candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing drug. In addition, we could be found liable for monetary damages, including treble damages and

attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Litigation may be necessary to defend against these claims. In addition, while it is our policy to require our employees and contractors who may be involved in the 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 develops intellectual property that we regard as our own. Our and their assignment agreements may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses ,and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively 38than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for our drug candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. For example, our platform is based on trade secrets that consist largely of expertise in carbohydrate chemistry and knowledge of carbohydrate biology. We do not believe that we can obtain patent protection for our platform. Thus, our competitors may use our methods, or acquire similar expertise, in order to develop glycomimetic drug candidates and progress these drug candidates through clinical development and commercialization, which could impair our ability to successfully commercialize our drug candidates. We seek to protect our trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Risks Related to Regulatory Approval of Our Drug Candidates and Other Legal Compliance MattersIf we or our collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize our drug candidates and our ability to generate revenue will be materially impaired. Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a drug candidate will prevent us or our collaborators from commercializing the drug candidate. We have not received approval to market any of our drug candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third- party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, applicable regulatory authorities. Our drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our ability to obtain marketing approval or prevent or limit commercial use. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the drug. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. Changes in marketing approval policies during the

development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted drug application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application, or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or ~~prevent~~ **39prevent** marketing approval of a drug candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved drug not commercially viable. ~~39If~~ **If** we experience delays in obtaining approval or if we fail to obtain approval of our drug candidates, the commercial prospects for our drug candidates may be harmed and our ability to generate revenue will be materially impaired. Even though we have obtained Orphan Drug designation for several of our drug candidates, we may not be able to obtain orphan drug marketing exclusivity for these or any of our other drug candidates. Regulatory authorities in some jurisdictions, including the United States and the European Union, or EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is 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 have obtained Orphan Drug designation from the FDA for uproleselan for the treatment of AML, as well as for GMI- 1359 for the treatment of osteosarcoma. However, in order to obtain marketing exclusivity in a particular jurisdiction, we must receive the first marketing approval of the drug for its intended indication. In addition, the orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Generally, if a drug with an orphan designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication for that time period. The applicable period is seven years in the United States and 10 years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the candidate from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. The FDA fast track designation and additional breakthrough therapy designation for uproleselan may not actually lead to a faster development or regulatory review or approval process. If a drug is intended for the treatment of a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for this disease or condition, the drug sponsor may apply for the FDA fast track designation. If fast track designation is obtained, the FDA may initiate review of sections of a ~~new drug application, or~~ NDA ~~,~~ before the application is complete. This " rolling review " is available if the applicant provides, and the FDA approves, a schedule for submission of the individual sections of the application. Although we have obtained a fast track designation from the FDA for uproleselan to treat AML and breakthrough therapy designation for uproleselan to treat AML, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Our fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development programs. Our fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures or that we will ultimately obtain regulatory approval of uproleselan. Failure to obtain marketing approval in international jurisdictions would prevent our drug candidates from being marketed abroad. In order to market and sell our drugs in the EU and any other jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the drug be approved for reimbursement before it can be approved for sale in that country. We or our ~~collaborators~~ **40collaborators** may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other ~~40countries~~ -- **countries** or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We or our collaborators may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our drugs in any market. A variety of risks associated with developing and marketing our drug candidates internationally could hurt our business. We or our collaborators may seek regulatory approval for uproleselan and our other drug candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including: ● differing regulatory requirements in foreign countries; ● the potential for so- called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally; ● unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; ● economic weakness, including inflation or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● foreign taxes, including withholding of payroll taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country; ● difficulties staffing and managing foreign operations; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● potential liability under the

Foreign Corrupt Practices Act or comparable foreign regulations; ● challenges enforcing our contractual and intellectual property rights, especially in foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ● business interruptions resulting from pandemic, epidemic or disease outbreaks or geo- political actions, including war and terrorism. Pursuant to the terms of our collaboration and license agreement, Apollomics is responsible for the clinical development and commercialization of uproleselan and GMI- 1687 in Greater China. ~~The continuation of COVID- 19 in China could have a material adverse effect on Apollomics' ability to develop these drug candidates in a timely manner due to disruptions in the region, travel restrictions, temporary closures of businesses and suspension of services and supplies.~~ Any ~~such~~ delay or disruptions in clinical development could result in the delay of any potential milestone payments to us under the license and collaboration agreement, which could have a material adverse effect on our financial position and results of operations. Any drug candidate for which we obtain marketing approval could be subject to post- marketing restrictions or recall or withdrawal from the market, and we may therefore be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates, when and if any of them are approved. Any drug candidate for which we obtain marketing approval, along with manufacturing processes, post- approval clinical data, labeling, advertising and promotional activities for such drug candidate, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a 41drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit its sales. The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the drug. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use, and if we do not market our drugs for their approved indications, we may be subject to enforcement action for off- label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our drugs, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have negative consequences, including: ● restrictions on such drugs, manufacturers or manufacturing processes; ● restrictions on the labeling or marketing of a drug; ● restrictions on product distribution or use; ● requirements to conduct post- marketing studies or clinical trials; ● warning letters; ● recall or withdrawal of the drugs from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● clinical holds; ● fines, restitution or disgorgement of revenue or profit; ● suspension or withdrawal of marketing approvals; ● refusal to permit the import or export of our drugs; ● product seizure; or ● injunctions or the imposition of civil or criminal penalties. Non- compliance with the EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of drugs for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU' s requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Our current and future business and relationships with customers and third- party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with third- party payors and customers 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, which may constrain the business or financial arrangements and relationships through which we conduct clinical research, sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient data privacy and security regulation by the U. S. federal and state governments 42and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs, such as Medicare and Medicaid; ● federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, and civil monetary penalty laws that prohibit individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as

their business associates **and covered subcontractors** that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ● the federal Open Payments program, pursuant to the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to " payments or other transfers of value " made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members, with disclosure of such information to be made by CMS on a publicly available website; and ● analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations 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 and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, individual imprisonment, 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, contractual damages, reputational harm, diminished profits and future earnings, ~~disgorgement~~ **43disgorgement** , exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the ~~43curtailment~~ -- **curtailment** or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of **enacted and proposed** legislative and regulatory ~~changes and proposed~~ changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. 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, which include major legislative initiatives to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government- funded health care programs, and increased governmental control of drug. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively PPACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, improve quality of care, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. **The** ~~Among the provisions of~~ PPACA ~~of importance to our business and potential drug candidates are: ● an annual , nondeductible fee on any entity that~~ **among other things, increased the minimum level of Medicaid rebates payable by** ~~manufactures~~ **manufacturers of** ~~or imports specified branded~~ -- **brand** ~~prescription~~ **name** drugs ~~and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs~~ ; **required collection of** ~~● an increase in the statutory minimum~~ rebates **for drugs paid by Medicaid managed care organizations; required manufacturers to participate in** a ~~manufacturer must pay under the Medicaid Drug Rebate Program to 23. 1 % and 13. 0 % of the average manufacturer price for branded and generic drugs, respectively; ● 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 non- compliance; ● a new Medicare Part D~~ coverage gap discount program, ~~in~~ **under** which ~~manufacturers~~ **they** must ~~now~~ agree to offer ~~70 %~~ point- of- sale discounts **(increased to 70 percent, effective as of January 1, 2019)** off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for ~~a~~ **the** manufacturer' s outpatient drugs to be covered under Medicare Part D; **imposed** ~~● extension of~~ a **non- deductible annual fee on pharmaceutical** ~~manufacturer~~ **manufacturers** ~~' s~~ **or importers who sell certain " branded prescription drugs " to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the** Medicaid **Drug** ~~rebate~~ **Rebate** ~~liability to covered~~ **Program are calculated for** drugs **that** ~~dispensed to individuals who~~ are ~~enrolled in Medicaid managed care organizations~~ **inhaled, infused, instilled, implanted, or injected** ; ~~● expansion~~ **expanded the types** of **entities eligible for the 340B drug discount program; expanded** 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 a manufacturer' s Medicaid rebate liability ~~; **created** ~~● expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; ● the new requirements under the federal Open Payments program and its implementing regulations; ● a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and44 ●~~ 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 established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending** . There ~~remain~~ **have been** judicial and Congressional challenges to certain aspects of PPACA. ~~President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or~~ **For example** ~~otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently~~ , ~~Congress considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax- based shared responsibility payment imposed by the PPACA~~ on ~~certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate ". In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA- mandated " Cadillac " tax on high- cost employer- sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole. " On~~ June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ~~ACA~~ **PPACA** is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the" donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and healthcare reform measures of the Biden administration will impact ~~ACA~~ **PPACA** and our business. Other legislative changes have been proposed and adopted since PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which began in 2013, and, due to subsequent legislative amendments, will stay in effect **until 2032,** unless additional Congressional action is taken. ~~Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester.~~ On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased ~~the~~ **44the** statute of limitations period for the government to recover overpayments to providers from three to five years. Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce reimbursement and / or coverage of our product candidates, if approved. Current and future healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high- expenditure, single- source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~will~~ **began to** take effect progressively starting in fiscal year 2023 **. On August 29** , ~~although~~ **2023, HHS announced** ~~they~~ **the** ~~may~~ **list of the first ten drugs that will** be subject to **price negotiations, although the Medicare drug price negotiation program is currently subject to** legal challenges. ~~Additionally,~~ **In response to** the Biden administration ~~released an additional~~ **' s October 2022** executive order **,** on ~~October~~ **February** 14, ~~2022~~ **2023** , ~~directing~~ HHS ~~to~~ **released a** report **outlining** ~~on how the~~ **three** ~~Center for Medicare and Medicaid Innovation can be further leveraged to test~~ new models for **testing by the CMS Innovation Center which will be evaluated on their ability to** ~~lowering --- lower drug the costs~~ **cost** ~~for Medicare~~ **of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced** ~~and~~ **an** ~~Medicaid beneficiaries~~ **initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of**

March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework . At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control ~~45pharmaceutical~~ -- **pharmaceutical** and biological product pricing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for drugs. 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 drug 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-marketing testing and other requirements. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any. In some countries, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our drug candidate to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. 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 operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our ~~operations~~ **45operations** also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Risks Related to ~~Employee Matters, Managing~~ Our **OperationsOur** ~~Growth and Other Risks Related to Our BusinessOur~~ future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the expertise of our senior management and the members of our scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may currently terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or employees. Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our drug pipeline toward scaling up for commercialization, sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our drug candidates. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on ~~46acceptable~~ -- **acceptable** terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our drug candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. ~~Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations. Our~~ **46Our** results of operations could be adversely affected..... in the financial markets. Our employees and employees of our collaborators may engage in misconduct or other improper activities, including non-

compliance with regulatory standards and requirements. We and our collaborators are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance ~~47with~~ -- **with** such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, or any such actions are instituted against any of our collaborators, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions and diminished royalties. **If** ~~Significant disruptions of our, or~~ **our** ~~our contractors' or vendors',~~ information technology systems or data ~~security incidents could result in significant financial~~ , ~~legal, regulatory, business and reputational harm to us. In the ordinary course of our~~ -- **or** ~~business, we and the~~ **those of** third parties upon which we rely ~~may~~ **, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; a disruption of our business operations, including our clinical trials; reputational harm; loss of revenue and profits; and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store,** process **, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process)** proprietary, confidential, and sensitive data, including personal data (such as health- related data), intellectual property, and trade secrets. We ~~may~~ rely upon third parties (such as service providers) for our data processing – related activities. We ~~may~~ share or receive sensitive data with or from third parties. We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. Cyberattacks, malicious internet- based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer " hackers, " threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to **operate our clinical trials and develop our** ~~produce~~ **products** ~~, sell and distribute our goods and services~~ . We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through **deep fakes, which may be increasingly more difficult to identify as fake, and** phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, **attacks enhanced or facilitated by artificial intelligence (AI),** telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments **. We rely on third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on CROs 47and CMOs. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties we rely upon experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties we rely upon fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award** . Similarly, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third- party information technology systems that support us and our services. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. Any of the previously identified or

similar..... our information technology systems and data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Any of the previously identified or similar threats could cause a security incident.A security incident could result in unauthorized,unlawful,or accidental acquisition,modification,destruction,loss,alteration,encryption,disclosure of,or access to data.A security incident could disrupt our ability (and that of third parties upon whom we rely) to conduct our business.For example,the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents.Certain data privacy and security obligations may require us to implement and maintain specific security measures,industry- standard or reasonable security measures to protect our information technology systems and data. Applicable data privacy and security ~~48obligations~~ -- **obligations** may require us to notify relevant stakeholders of security incidents **, including affected individuals, customers, regulators, and investors** . Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); **interruptions in our operations, including disruption of our uproleselan development program;** additional reporting requirements and / or oversight; **interruptions or** restrictions on processing **sensitive** data (~~including personal~~ **which could result in delays in obtaining, or our inability to obtain, regulatory approvals and significantly increase our costs to recover or reproduce the** data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; **diversion of management attention;** interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. **In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive 48information of the Company could be leaked, disclosed, or revealed as a result of or in connection with use of generative artificial intelligence (AI) technologies by our employees, personnel or vendors. We are subject to stringent and changing U. S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies, and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue and profits; and other adverse business impacts. In the ordinary course of business, we process personal data and other sensitive data, including proprietary and confidential business data, trade secrets, intellectual property, clinical trial participant data, and other sensitive third- party data. Our data processing activities subject us to numerous data privacy and security obligations, such as federal, state, local and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations governing the processing and security of personal data. These obligations may change, are subject to differing interpretations and may be inconsistent among jurisdictions or conflict. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business; affect our (or the third parties upon which we rely) ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal data; necessitate the acceptance of more onerous obligations in our contracts; result in liability; or impose additional costs on us. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model. Outside the U. S., an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union' s** General ~~Risks~~ **Data Protection Regulation (GDPR) (EU) 2016 / 679, or the EU GDPR and the United Kingdom' s GDPR (UK GDPR), or collectively GDPR, impose strict requirements on the processing of personal data. Under the GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines in the event of violations. Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each case, 4 % of annual global revenue, whichever is greater; or private litigation** ~~Related~~ **related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U. S. in compliance with law, such as the EEA standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U.**

S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U. S. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the U. S., or if the requirements for a legally- compliant transfer are ~~to~~ **too** ~~Ownership~~ **onerous, we could face significant adverse consequences, including the interruption or degradation** of **our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some EEA regulators have prevented companies from transferring personal data out of the EEA for allegedly violating the GDPR' s cross- border data transfer limitations. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of 49the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health data. See "** Our ~~Common StockAn operations. Our~~ results of operations could be adversely affected by general conditions in the global economy and in the global financial markets.A severe or prolonged economic downturn,or additional global financial crises,including related to ~~health epidemics~~ **the COVID- 19 pandemic** or **the** armed ~~conflicts~~ - **conflict in Ukraine** and ~~geopolitical tensions around~~ the ~~world~~ **surrounding region** ,could result in a variety of risks to our business,including weakened demand for our product candidates,if approved,or our ability to raise additional capital when needed on acceptable terms,if at all.A weak or declining economy could also strain our suppliers,possibly resulting in supply disruption.Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the **current** economic climate and financial market conditions could adversely impact our business. In addition,our available cash and cash equivalents are held in accounts managed by third party financial institutions and consist of cash in our operating accounts and cash invested in ~~U.S.Government~~ money market funds.At any point in time,the funds in our operating accounts may exceed the Federal Deposit Insurance Corporation insurance limits.While we monitor the cash balances in our operating accounts and adjust the cash balances as appropriate,these cash balances could be impacted if the underlying financial institutions fail.We can provide no assurances that access to our operating cash or invested cash and cash equivalents will not be impacted by adverse conditions in the financial **markets. Our** active trading market for our common stock may not be sustained. Although our common stock is listed on The Nasdaq Global Market, we cannot assure you that an active trading market for our shares will be sustained. If an active market for our common stock is not sustained, it may be difficult for investors in our common stock to sell shares without depressing the market price for the shares or to sell the shares at all. The trading price of our common stock has been and is likely to continue to be volatile. Our stock price from time to time has been volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including: ● announcements relating to development, regulatory approvals or commercialization of our drug candidates; ● actual or anticipated variations in our operating results; ● changes in financial estimates by us or by any securities analysts who might cover our stock; ● conditions or trends in our industry; ● changes in laws or other regulatory actions affecting us or our industry, such as drug pricing and reimbursement; ● stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry; ● announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures; ● announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; ● capital commitments; ● investors' general perception of our company and our business; ● disputes concerning our intellectual property or other proprietary rights; **51** ● recruitment or departure of key personnel; and ● sales of our common stock, including sales by our directors and officers or specific stockholders. In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, which has resulted in volatile stock prices ~~49for~~ -- **for** many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, including worsening economic conditions and other adverse effects or developments relating to political, regulatory and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance. In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources from our business. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. We have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline. The issuance of additional stock in connection with financings, acquisitions, investments, our stock

incentive plan, our employee stock purchase plan or otherwise will dilute all other stockholders. Our certificate of incorporation authorizes us to issue up to 100, 000, 000 shares of common stock and up to 5, 000, 000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our stock incentive plan, our employee stock purchase plan or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline. If a substantial number of our total outstanding shares are sold into the market, or if the market perceives that such sales may occur, it could cause the market price of our common stock to drop 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 if the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates. In addition, we have filed registration statements on Form S- 8 registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements are available for sale in the public market subject to vesting arrangements and exercise of options, as well as Rule 144 in the case of our affiliates. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. ~~Provisions~~ **52Provisions** in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result. There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by some or all of our stockholders. For example, our board of directors has the authority to issue up to 5, 000, 000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our ~~50stockholders~~ **stockholders** may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders. Our charter documents also contain other provisions that could have an anti- takeover effect, including: ● only one of our three classes of directors is elected each year; ● stockholders are not entitled to remove directors other than by a 66 2 / 3 % vote and only for cause; ● stockholders are not permitted to take actions by written consent; ● stockholders cannot call a special meeting of stockholders; and ● stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings. In addition, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock. Our certificate of incorporation also provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations of The Nasdaq Global Market. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting and perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may in the future discover areas of our internal financial and accounting controls and procedures that need improvement. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are unable to maintain proper and effective internal controls in the future, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal controls over financial reporting are not effective. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. ~~We~~ **53We** do not anticipate paying any cash dividends on our common stock in the foreseeable future and our stock may not appreciate in value. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. There is no guarantee that shares of our common stock will appreciate in value or that the price at which our stockholders have purchased their shares will be able to be maintained. We incur increased costs and demands upon management as a result of being a public company. As a public company listed in the United States, we incur, and will continue to incur now that we have ceased to be an " emerging growth company, " significant legal, accounting and other costs. These costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public ~~51disclosure~~ **disclosure**, including regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time- consuming. These laws,

regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If we do not comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management. ITEM 1B. UNRESOLVED STAFF COMMENTSNone. ITEM ~~2~~ **1C** . **CYBERSECURITYRisk management and strategy We operate** ~~PROPERTIESOur principal offices occupy approximately 42, 000 square feet of leased office space~~ in ~~Rockville~~ **the biopharmaceutical sector** , **which is** ~~Maryland, pursuant to~~ a ~~lease agreement~~ **highly regulated sector subject to various cybersecurity risks** that **could adversely affect** ~~expires in October 2023. We believe that our properties are generally in good condition, well maintained, suitable and adequate to carry on~~ our business ~~. We believe our capital resources are sufficient to lease any additional facilities required to meet our expected growth needs. ITEM 3. LEGAL PROCEEDINGSFrom time to time~~ , ~~we are subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or~~ financial condition ~~. ITEM 4. MINE SAFETY DISCLOSURESNot applicable. PART IIITEM 5. MARKET FOR REGISTRANT' S COMMON EQUITY~~ , ~~RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIESMarket~~ **and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; disruption of our clinical trials, manufacturing or supply chain; violation of privacy laws and other litigation and legal risk; and reputational risk. We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including clinical trial data, intellectual property, confidential information that is proprietary, strategic, financial or competitive in nature, and personal data (" Information Systems and Data "). Our Information Technology personnel help identify, assess and manage cybersecurity threats and risks that could affect our business and Information Systems and Data, and support our efforts to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment. We use various methods and tools to identify, assess and manage our cybersecurity threats and risks, including,** for ~~Common StockOur common stock is listed~~ **example, automated tools, industry reports about cybersecurity risks and threats to our industry, third party threat assessments, and penetration testing. In addition, we utilize encryption for certain data at rest and maintain certain network security controls, such as firewalls and virtual private networks. We also conduct monitoring for certain systems and access controls in place for certain environments and systems, as well as asset management, tracking and disposal associated with onboarding and offboarding of personnel. We maintain cybersecurity insurance. Depending** on ~~The Nasdaq Global Market under~~ the ~~symbol " GLYC~~ **environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data** . " ~~Dividend PolicyWe~~ **For example, we** have **implemented and maintain** ~~never declared or paid any~~ **an incident response plan** ~~dividends on our common stock. We anticipate that we will retain all of our future earnings~~ , ~~if any, for use in the operation~~ and **we 54** ~~expansion of our business and do not anticipate paying cash dividends in the foreseeable future. 52~~