Risk Factors Comparison 2025-01-28 to 2024-02-15 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10- K, including the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our consolidated financial statements and the accompanying notes and the information contained in our other public filings before deciding whether to invest in shares of our common stock. We cannot assure you that any of the events described below will not occur. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. If any of the following risks occur, our business, financial condition, results of operations, and future prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment. Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability. Our net loss was $ **193. 6 million and $** 143. 9 ~~million and $ 180. 4~~ million for the fiscal years ended November 30, **2024 and** 2023 ~~and 2022~~, respectively. As of November 30, ~~2023~~ **2024**, we had an accumulated deficit of $ ~~545~~ **738**. ~~2~~ **8** million. To date, we have not generated any revenue from product sales and have financed our operations primarily through our collaborations and sales of our equity interests. We are in the early stages of development of our drug candidates. Our lead drug candidates, NX- 5948, NX- 2127 and NX- 1607, are in the early stages of clinical development. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our operating expenses and capital expenditure requirements will increase substantially if and as we: • increase enrollment in and further ~~development~~ ---- **develop** ~~of our Phase 1 clinical trials of~~ our drug candidates NX- 5948, NX- 2127 and NX- 1607 **through Phase 1 clinical trials**; • submit investigational new drug applications (INDs) and initiate clinical trials of our other drug candidates; • enter advanced clinical development and scale up external manufacturing capabilities to supply clinical trials; • expand the capabilities of our ~~DELigase~~ **DEL- AI** platform and apply our ~~DELigase~~ **DEL- AI** platform to advance additional drug candidates into preclinical and clinical development; • conduct process development for manufacturing of our drug candidates; • seek marketing approvals for any drug candidates that successfully complete clinical trials; • prepare for negotiations with the pricing authorities and submission to the health technology appraisal (HTA) bodies; • ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain marketing approval; • expand, maintain and protect our intellectual property portfolio; • hire additional clinical, regulatory, manufacturing, quality assurance and scientific personnel; and • add operational, financial and management information systems and personnel to support our research, product development and future commercialization efforts and support our operations as a public company. Our expenses could increase beyond our expectations if we are required by the U. S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) or other regulatory authorities to perform trials in addition to those we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our planned clinical trials or the development of any of our drug candidates. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. 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, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We have never generated revenue from product sales and may never be profitable. We are in the early stages of clinical development of our **lead** drug candidates NX- 5948, NX- 2127 and NX- 1607. We expect that it will be many years, if ever, before we have a drug candidate ready for commercialization. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. To become and remain profitable, we must succeed in developing, obtaining marketing approval for and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, discovering additional drug candidates, establishing and maintaining arrangements with third parties for the manufacture of clinical supplies of our drug candidates, obtaining marketing approval for our drug candidates and manufacturing, marketing, selling and obtaining reimbursement for any products for which we may obtain marketing approval. If one or more of the drug candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved drug candidate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. We will need substantial additional funding. If we are unable to raise capital when needed, we may be required to delay, limit, reduce or terminate our research or product development programs or future commercialization efforts. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we conduct our Phase 1 clinical trials of NX- 5948, NX- 2127 and NX- 1607 ~~, grow our pipeline~~ **and any future development** of **our** drug candidates, **grow our pipeline of drug candidates,** expand the breadth of our ~~DELigase~~ **DEL- AI** platform, continue research and development and initiate additional clinical trials of and potentially seek marketing approval for our lead programs and other drug candidates. In addition, if we obtain marketing approval for any of our

drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, reimbursement and sales and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research, product development programs or any future commercialization efforts or grant rights to develop and market drug candidates that we otherwise would prefer to develop and market ourselves. We had cash, cash equivalents and marketable securities of $ ~~295~~ **609** . ~~3~~ **6** million as of November 30, ~~2023~~ **2024** . We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months. However, our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect, and we may need to seek additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. Our future capital requirements will depend on many factors, including: • the progress, costs and results of our Phase 1 clinical trials for NX- 5948, NX- 2127 and NX- 1607 and any future clinical development of such drug candidates; • the scope, progress, costs and results of preclinical and clinical development for our other drug candidates and development programs; • the number and development requirements of other drug candidates that we pursue; • the scope of, and costs associated with, future advancements to our ~~DELigase~~ **DEL- AI** platform; • the success of our collaborations with Gilead Sciences, Inc. (Gilead), Sanofi S. A. (Sanofi) and Seagen Inc. (now a part of Pfizer Inc. (Pfizer)) and any other collaborations we may establish; • the costs, timing and outcome of regulatory review of our drug candidates **; • the costs, timing and outcome of negotiations with pricing authorities and health technology assessment authorities** ; • 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 • our ability to establish additional collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our drug candidates. We will need to raise substantial additional capital to complete the development and commercialization of our drug candidates. In addition, our drug candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives. Adequate additional funds may not be available to us on acceptable terms, or at all. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Although we may receive potential future milestone payments under our collaborations with Gilead, Sanofi and Pfizer, we do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of common stock. 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 acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us. Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability. We commenced operations in 2009, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential drug candidates, undertaking preclinical studies, establishing arrangements with third parties for the manufacture of initial quantities of our drug candidates and conducting early- stage clinical trials. Our lead drug candidates are in the early stages of clinical development and their risk of failure is high. We have not yet demonstrated our ability to successfully: complete any clinical trials, including large- scale, pivotal clinical trials; obtain marketing approvals; manufacture a commercial- scale product or arrange for a third party to do so on our behalf; or conduct market access, sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as an early- stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. 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 results of operations 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 performance. Risks Related to the Discovery and Development of Our Drug Candidates We are early in our development efforts. Our lead drug candidates, NX- 5948, NX- 2127 and NX- 1607, are in the early stages of clinical development. If we are unable to advance our drug candidates through clinical development, develop, obtain regulatory approval for and commercialize our drug candidates or experience significant delays in doing so, our business may be materially harmed. We are early in our development efforts. Our lead drug candidates, NX- 5948, NX- 2127 and NX- 1607, are in the early stages of clinical development and their risk of failure is high. We have invested substantially all of our efforts and financial resources in building our ~~DELigase~~ **DEL- AI** platform, in the identification and preclinical development of

our current drug candidates and in the preparation for and initiation of Phase 1 clinical trials for our lead drug candidates **, as well as the preparation to advance NX- 5948 into a Phase 2 clinical trial, anticipated in 2025** . Our ability to generate revenue from product sales, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our drug candidates. The success of our drug candidates will depend on several factors, including the following: • sufficiency of our financial and other resources; • successful completion of preclinical studies; • successful submission of INDs or Clinical Trial Applications and initiation of clinical trials; • successful patient enrollment in, and completion of, clinical trials; • receipt and related terms of marketing approvals from applicable regulatory authorities; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates as well as obtaining relevant exclusivity extensions (due to the conduct of pediatric studies); • making arrangements with third- party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our drug candidates; • achieving desirable therapeutic properties for our drug candidates' intended indications; • establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; • acceptance of our products, if and when approved, by patients, the medical community and third- party payors; • obtaining and maintaining third- party coverage and adequate reimbursement; • establishing a continued acceptable safety profile of our drug candidates and maintaining such a profile following approval; and • effectively competing with other therapies. If we do not successfully 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 could materially harm our business. Moreover, if we do not receive regulatory approvals, we may not be able to continue our operations. In addition, we filed for and received an Innovation Passport designation for NX- 1607 in the United Kingdom (UK) in February 2022. The Innovation Passport is the mandated entry point to the Innovative Licensing and Access Pathway (ILAP) in the UK to facilitate approval of and market access to an innovative medicine. Grant of the Innovation Passport paves the way for enhanced engagement with key stakeholders such as the Medicines and Healthcare products Regulatory Agency (MHRA), health technology agencies in the UK such as the National Institute for Health and Care Excellence ~~(NICE)~~ or the Scottish Medicines Consortium ~~(SMC)~~ and NHS England. However, although the goal of ILAP and the Innovation Passport is to reduce the time to market and enable earlier patient access, they do not accelerate conduct of clinical trials or mean that the regulatory requirements are less stringent, nor do they ensure that any NX- 1607 marketing authorization application (MAA) will be approved or that any approval will be granted within any particular timeframe. Despite receiving an Innovation Passport designation, we may decide to delay or forego the commercialization of NX- 1607 in the UK or the development may otherwise not proceed. One of our approaches to the discovery and development of drug candidates based on our targeted protein degradation platform is unproven, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any products. Treating diseases using targeted protein degradation is a new treatment modality. Our future success depends on the successful development of this novel therapeutic approach. Very few small molecule drug candidates designed to control cellular protein levels, such as our BTK degraders, have been tested in humans, none have been approved in the United States or Europe, and the data underlying the feasibility of developing these therapeutic products is both preliminary and limited. Discovery and development of targeted protein degraders that harness ligases to degrade protein targets have been impeded largely by the complexities and limited understanding of the functions, biochemistry and structural biology of E3 ligases as well as by challenges of engineering compounds that promote protein- protein interactions. We believe that our targeted protein degrader drug candidates may offer an improved therapeutic approach by removing the disease- causing proteins instead of simply inhibiting their activities. However, the scientific research that forms the basis of our efforts to develop our targeted protein degrader drug candidates is ongoing and the scientific evidence to support the feasibility of developing targeted protein degrader- based therapeutic treatments is both preliminary and limited. Further, certain patients have shown inherent (primary) resistance to approved BTK inhibitors and other patients have developed acquired (secondary) resistance to these inhibitors. Both NX- 5948 and NX- 2127 degrade BTK with mutations that confer resistance to currently marketed BTK inhibitors, and we believe that preliminary data from our ongoing Phase 1 trials of NX- 5948 and NX- 2127 may provide evidence of clinical benefit to patients with such resistance mutations. However, any inherent primary or acquired secondary resistance to our BTK degraders in patients would prevent or diminish their clinical benefit. We are in the early stages of clinical development of NX- 5948 and NX- 2127 and we currently have limited safety data of NX- 5948 and NX- 2127 in humans. Although some of our drug candidates have produced observable results in animal studies, these drug candidates may not demonstrate the same chemical and pharmacological properties in humans, and may interact with human biological systems in unforeseen, ineffective or harmful ways. As such, there may be adverse effects from treatment with any of our current or future drug candidates that we cannot predict at this time. Additionally, the regulatory approval process for novel drug candidates such as ours can be more expensive and take longer than for other, better- known or extensively- studied drug candidates. Although other companies are also developing therapeutics based on targeted protein degradation, no regulatory authority has granted approval for any such therapeutic. As a result of these factors, it is more difficult for us to predict the time and cost of targeted protein degrader drug candidate development, and we cannot predict whether targeted protein degradation will result in the development and marketing approval of any products. Any development problems we experience in the future related to any of our targeted protein degrader research programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Advancing our targeted protein degrader drug candidates creates significant challenges for us, including: • educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating our drug candidates, if approved, into treatment regimens; and • establishing the sales and marketing capabilities to gain market acceptance, if approved. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate, or from commercializing any targeted protein degrader drug candidates we may develop on a timely or profitable basis, if at all. Drug development is a lengthy and expensive process, with

an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates. Our lead drug candidates are in the early stages of clinical development and their risk of failure is high. We are unable to predict when or if any of our drug candidates will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Before we can commence clinical trials for a drug candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or similar regulatory authorities outside the United States will accept our proposed clinical programs or if the outcome of our preclinical testing and studies ultimately will support the further development of our programs. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through adequate and well- controlled clinical trials that our drug candidates are safe and effective for use in treating specific conditions in order to obtain marketing approvals for their commercial sale. Success in preclinical studies and early- stage clinical trials does not mean that any future larger registration clinical trials will be successful because drug candidates in later- stage clinical trials may fail to demonstrate safety and efficacy to the satisfaction of the FDA and non- U. S. regulatory authorities despite having progressed through preclinical studies and early- stage clinical trials. Drug candidates that have shown promising results in preclinical studies and early- stage clinical trials may still suffer significant setbacks in subsequent larger registration clinical trials. Additionally, the outcome of preclinical studies and early- stage clinical trials may not be predictive of the success of later- stage clinical trials. We may experience numerous unforeseen events during, or as a result of, clinical trials, that could delay or prevent our ability to receive marketing approval or commercialize our drug candidates, including: • we may experience delays in reaching, or may fail to reach, a consensus with regulators on trial design; • 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, including as a result of delays in the testing, validation, manufacturing and delivery of drug candidates to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions; • we may experience delays in reaching, or may fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • regulators or institutional review boards (IRBs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; • we may face delays under human tissue act legislation and restrictions across various jurisdictions; • we may experience difficulty in designing clinical trials and in selecting endpoints for diseases that have not been well- studied and for which the natural history and course of the disease is poorly understood; • the selection of certain clinical endpoints may require prolonged periods of clinical observation or analysis of the resulting data; • 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 drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials; • we may have to suspend or terminate clinical trials of our drug candidates for various reasons, including a partial or full clinical hold based on a finding that our drug candidates have undesirable side effects or other unexpected characteristics, or that the participants are being exposed to unacceptable health risks; • 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 IRBs may require that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements; • clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • 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; • regulators may revise the requirements for approving our drug candidates, or such requirements may not be as we anticipate; • any future collaborators that conduct clinical trials may face any of the above issues and may also conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us; and • disruptions caused by macroeconomic, political and market conditions, including supply chain disruptions, may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same drug candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate safety and efficacy sufficient to obtain marketing approval for our drug candidates. 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 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 changes in the way the product is administered; or • have the product removed from the market after obtaining marketing approval. Our product development costs also will increase if we experience delays in preclinical studies or clinical trials or in obtaining 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 could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates, which may harm our business, results of operations, financial condition and prospects. Further, cancer therapies sometimes are characterized as first- line, second- line or third- line, and the FDA often approves new therapies initially only for third- line or later use, meaning for use after two or more other treatments have failed. When cancer is detected early enough, first- line therapy, usually chemotherapy, hormone therapy, immunotherapy, radiation therapy, surgery, targeted therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third- line therapies are administered to patients when prior therapy was ineffective. Our current and planned clinical trials for our drug candidates NX- 5948, NX- 2127 and NX- 1607 are and will be with patients who have received one or more prior treatments. Subsequently, for those drug candidates that prove to be sufficiently beneficial, if any, we may seek approval potentially as a first- line therapy, but any drug candidates we develop, even if approved, may not be approved for first- line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. If serious adverse events, undesirable side effects or unexpected characteristics are identified during the development of any drug candidates we may develop, we may need to abandon or limit our further clinical development of those drug candidates. We have recently begun to evaluate our lead drug candidates in human clinical trials, and there have been very few clinical trials to date involving small molecule drug candidates designed to control cellular protein levels through targeted protein degradation. It is impossible to predict when or if any drug candidates we may develop will prove safe in humans. There is a limited safety data set for the effects of NX- 5948, NX- 2127 and NX- 1607 in animals and we only recently have begun to test the safety of our drug candidates in humans. There can be no assurance that our current drug candidates or any future drug candidate will not cause undesirable side effects. Unforeseen side effects from our drug candidates could arise at any time during preclinical or clinical development. A potential risk in any protein ~~modulation~~ **degradation** product is that healthy proteins or proteins not targeted for ~~modulation~~ **degradation** will be ~~modulated~~ **degraded** or that the ~~modulation~~ **degradation** of the targeted protein in itself could cause adverse events, undesirable side effects or unexpected characteristics. It is possible that healthy proteins or proteins not targeted for ~~modulation~~ **degradation** could be ~~modulated~~ **degraded** by our drug candidates in any of our current or future preclinical studies or clinical trials. There also is the potential risk of delayed adverse events following treatment with our drug candidates. If any drug candidates we develop are associated with serious adverse events or undesirable side effects, or have characteristics that are unexpected, including in preclinical studies, we may need to abandon their development or limit development to certain uses or subpopulations in which the adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects. For example, increased bleeding risk and cardiac arrhythmia such as atrial fibrillation have been reported side effects of approved BTK inhibitors. Furthermore, NX- 1607 could activate the immune response to unsafe levels and may have the potential to induce hypercytokinemia, or cytokine storm, which is the overstimulation of immune cells and subsequent overproduction of their activating compounds. Many drug candidates that initially showed promise in early- stage testing for treating cancer or other diseases later have been found to cause side effects that prevented further clinical development of the drug candidates or limited their competitiveness in the market. The results of preclinical studies and early- stage clinical trials may not be predictive of future results. Initial success in clinical trials may not be indicative of results obtained **in later- stage trials or** when these trials are completed ~~or in later- stage trials~~. The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early- stage clinical trials we commence may not be predictive of the results of the later- stage clinical trials **or when these trials are completed**. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. In particular, the small number of patients in our planned early clinical trials may make the results of these trials less predictive of the outcomes of later clinical trials. For example, even if successful, the results of our initial clinical trials for NX- 5948, NX- 2127 and NX- 1607 may not be predictive of the results of further clinical trials of these drug candidates or any of our other drug candidates. Moreover, preclinical and clinical data often are susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials nonetheless have failed to obtain marketing approval of their products. Our future clinical trials may not ultimately be successful or support further clinical development of any of our drug candidates. There is a high failure rate for drug candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies and clinical trials. Any such setbacks in our clinical development could materially harm our business, results of operations, financial condition and prospects. Interim top- line and preliminary data from our planned clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim top- line or preliminary data from our planned clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top- line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation, business, results of operations, financial condition and prospects. If we experience delays or difficulties in enrolling patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. In particular, we are currently conducting

Phase 1 clinical trials for each of our lead drug candidates ~~:~~ NX- 5948, NX- 2127 and NX- 1607 **, and we expect to initiate a Phase 2 clinical trial of NX- 5948 in 2025** . We cannot predict how difficult it will be to enroll patients for these trials. Therefore, our ability to identify and enroll eligible patients for our NX- 5948, NX- 2127 and NX- 1607 clinical trials may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who otherwise would be eligible for our planned clinical trials instead may enroll in clinical trials of our competitors' drug candidates. Moreover, the size of the relevant patient populations for the diseases that our lead drug candidates target is small, and as more companies begin to focus attention and resources on drug candidates to treat the same indications as our drug candidates, we may experience delays or be unable to successfully recruit and enroll a sufficient number of eligible patients in our clinical trials. Patient enrollment is affected by other factors including: • the severity of the disease under investigation; • the size of the patient population and process for identifying patients; • the availability and efficacy of approved medications for the disease under investigation; • the eligibility criteria for the trial in question; • the perceived risks and benefits of the drug candidates under study; • the efforts to facilitate timely enrollment in clinical trials; • physicians' attitudes and practices with respect to clinical trial enrollment; • the burden on patients due to inconvenient procedures; • the ability to monitor patients adequately during and after treatment; and • the proximity and availability of clinical trial sites for prospective patients. Our inability to enroll a sufficient number of patients for our current or planned clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our current or planned clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. 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 managerial resources, we focus on research programs and drug candidates that we identify for specific indications. 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 products 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 products. 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 royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate. The manufacture of drugs is complex, and we and our third- party manufacturers are early in our manufacturing efforts. We have established manufacturing relationships with a limited number of suppliers to manufacture raw materials and the drug substance of any drug candidate for which we are currently pursuing, or may in the future pursue, preclinical or clinical development. Our systems for complying with current good manufacturing practices (cGMPs), manufacturing process development with our third- party manufacturers and scale- up are at an early stage. The actual cost to manufacture and process our drug candidates could be greater than we expect and could materially and adversely affect the commercial viability of our drug candidates. We or any of our third- party manufacturers may encounter difficulties in production, including contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If we or any of our third- party manufacturers encounter such difficulties, our ability to provide supply of our current or future drug candidates for clinical trials, our ability to obtain marketing approval or our ability to provide supply of our drug candidates for patients, if approved, could be delayed or stopped. For example, in October 2023, following our communication to the FDA of our intention to transition to an improved manufacturing process for NX- 2127, the FDA placed a partial clinical hold on our ongoing Phase 1 clinical trial evaluating NX- 2127. ~~Currently- enrolled patients who are deriving clinical benefit may continue to receive treatment in accordance with the ongoing study protocol, but no additional patients may be enrolled until the partial clinical hold is resolved.~~ We ~~remain~~ actively engaged in discussions with FDA as part of our efforts to lift the partial clinical hold ~~. However~~ , **and in March 2024, the FDA lifted the partial clinical hold.** ~~there~~ **There** can be no assurance that we can address ~~the~~ **any** issues resulting in ~~the~~ **any** partial **or full** clinical hold in a timely manner or at all, and we may incur additional expenses in connection with our efforts to **address a partial or full clinical hold or** advance our **clinical** ~~NX- 2127 program~~ **programs** . We may not be successful in our efforts to identify or discover additional potential drug candidates. A key element of our strategy is to apply our ~~DELigase~~ **DEL- AI** platform to address a broad array of targets and new therapeutic areas. The therapeutic discovery activities we are conducting may not be successful in identifying drug candidates that are useful in treating hematologic cancers, immune- mediated diseases or any other diseases. Our research programs initially may show promise in identifying potential drug candidates, yet fail to yield drug candidates for clinical development for a number of reasons, including: • the research methodology used may not be successful in identifying potential drug candidates; • potential drug candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval or achieve market acceptance; or • potential drug candidates may not be effective in treating their targeted diseases. Research programs to identify new drug candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential drug candidate that ultimately proves to be unsuccessful. If we are unable to identify suitable drug candidates for preclinical and clinical development, we will not be able to obtain revenues from the sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price. We may not be successful in our efforts to expand the breadth of our ~~DELigase~~ **DEL- AI** platform. A key element of our strategy is to expand the capabilities of our ~~DELigase~~ **DEL- AI** platform and leverage our platform to discover, develop and potentially commercialize additional drug candidates beyond our current portfolio to target diseases in a wide range of organ systems and

tissues and treat various disease states. These enhancements require substantial technical, financial and human resources, and may not result in the discovery or development of additional drug candidates or therapies. We may pursue what we believe is a promising opportunity to leverage our platform only to discover that certain of our risk or resource allocation decisions were incorrect or insufficient, or that individual products or our science in general has technology or biology risks that were previously unknown or underappreciated. Our strategy of pursuing the value of our ~~DELigase~~ **DEL- AI** platform over a long time horizon and across a broad array of human diseases may not be effective. In the event material decisions in any of these areas turn out to be incorrect or sub- optimal, we may experience a material adverse impact on our business and ability to fund our operations and we may never realize what we believe is the potential of our ~~DELigase~~ **DEL- AI** platform. We face substantial competition in an environment of rapid technological change, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new drug products is highly competitive. Moreover, the biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face and will continue to face competition from third parties that use protein ~~modulation~~ **degradation** , antibody therapy, adoptive cell therapy, inhibitory nucleic acid, gene editing or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. The competition is likely to come from multiple sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We are aware of a number of biotechnology companies focused on developing small molecules that degrade target proteins or inhibit E3 ligases, **many** ~~including, but not limited to, Accutar Biotechnology Inc., Arvinas, Inc., BeiGene, Ltd., BioTheryX, Inc., C4 Therapeutics, Inc., Cullgen Inc., Foghorn Therapeutics Inc., HotSpot Therapeutics, Inc., Kymera Therapeutics, Inc. and Monte Rosa Therapeutics, all~~ of which currently are in preclinical or clinical development. In addition, certain large pharmaceutical companies have disclosed investments in this field ~~, including AbbVie Inc., Amgen Inc., AstraZeneca plc, Bayer AG, Bristol- Myers Squibb Company, Genentech, Inc., GlaxoSmithKline plc and Novartis International AG~~ . Furthermore, we are aware of multiple other BTK degrader programs in clinical development ~~, including programs from AbbVie Inc., Accutar Biotechnology, Inc., BeiGene, Ltd, Haisco Pharmaceutical Group Co., Ltd. and Ubix Therapeutics, Inc~~ . Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Further, 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 also may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. All of these competitors 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 commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could prevent us from obtaining the orphan designation in the European Union (EU) and / or in the UK and result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our drug candidates are approved, we expect that they will be priced at a significant premium over competitive generic products. If we do not achieve our projected development goals in the time frames we expect and announce, the commercialization of our products may be delayed and, as a result, our stock price may decline. From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings and may be associated with payments from third- party collaborators such as Gilead, Sanofi or Pfizer. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, our revenue may be lower than expected, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline. Our estimated market opportunities for our drug candidates are subject to numerous uncertainties and may prove to be inaccurate. If we have overestimated the size of our market opportunities, our future growth may be limited. Our estimated addressable markets and market opportunities for our drug candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence and internally generated data and assumptions. We have not independently verified any third- party information and cannot be assured of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third- party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may prove inaccurate. Although we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this Annual Report on Form 10- K. If this third- party or internally generated data prove to be inaccurate or if we make errors in our assumptions based on that data, our actual market may be more limited than we estimate it to be. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business

resources, which could harm our business **. The biopharmaceutical industry is subject to extensive regulatory obligations and policies that are subject to change, including due to judicial challenges. On June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) " must exercise their independent judgment " and " may not defer to an agency interpretation of the law simply because a statute is ambiguous. " The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict but could have a material adverse effect on our business and financial condition. For example, certain of these changes could impose additional limitations on the rates we will be able to charge for our future products or the amounts of reimbursement available for our future products from governmental agencies or third- party payors** . Risks Related to Dependence on Third Parties We expect to depend on collaborations with third parties for the research, development and commercialization of certain of the drug candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those drug candidates. We have sought third- party collaborators for the research, development and commercialization of some of our targeted protein degrader programs. For example, in June 2019 we entered into a collaboration with Gilead; in December 2019 we entered into a collaboration with Sanofi, which was subsequently expanded and amended in January 2021; and in September 2023 we entered into a collaboration with Seagen Inc. (now a part of Pfizer). Each of the foregoing collaborations requires us to conduct certain research activities. Our likely collaborators for any other collaboration arrangements include large and mid- size pharmaceutical companies, biotechnology companies and universities. These and any future arrangements with third parties limit our control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any drug candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into. Collaborations involving our research programs or any drug candidates we may develop, including our collaborations with Gilead, Sanofi and Pfizer, pose risks to us, including: • Collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations with us. • Collaborators may not pursue development and commercialization of any drug candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator' s strategic focus or available funding or external factors such as an acquisition or business combination that diverts resources or creates competing priorities. • Gilead and Sanofi have broad option rights to select up to five targets each, and Pfizer has option rights to multiple targets, for exclusive targeted protein degrader development, so long as not excluded by us under the terms of each collaboration, and may select targets we are considering but have not taken sufficient action to exclude under each collaboration. • 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. • Collaborators could develop independently, or develop with third parties, products that compete directly or indirectly with our products or drug candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours. • Collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products. • Collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation. For example, Gilead, Sanofi and Pfizer have the first right to enforce or defend certain intellectual property rights under the applicable collaboration arrangement with respect to particular licensed programs, and although we may have the right to assume the enforcement and defense of such intellectual property rights if the collaborator does not, our ability to do so may be compromised by their actions. • Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or drug candidates or that result in costly litigation or arbitration that diverts management attention and resources. • We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control. For example, Sanofi may terminate its agreement with us if we undergo a change of control. • Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates. For example, each of Gilead, Sanofi and Pfizer can terminate its agreement with us in its entirety or with respect to a specific target for convenience upon written notice or in connection with a material breach of the agreement by us that remains uncured for a specified period of time. • Collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner, or at all. For instance, if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated. If our collaborations do not result in the successful development and commercialization of products, 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. If we do not receive the funding we expect under these agreements, our development of drug candidates could be delayed, and we may need additional resources to develop drug candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Moreover, all of the risks relating to product development, marketing approval and commercialization described in this Annual Report on Form 10-

K apply to the activities of our collaborators. We may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any drug candidates we may develop. These relationships may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, issue securities that dilute the ownership interest of our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time- consuming and complex. Our ability to reach a definitive collaboration agreement will depend upon, among other things, our assessment of the proposed collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of several factors. If we license rights to any drug candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We may seek to establish additional collaborations. If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans. We plan to continue to selectively pursue collaborations with leading biopharmaceutical and biotechnology companies with development and commercial expertise and capabilities. We face significant competition in attracting appropriate collaborators to advance the development of any drug candidates for which we may seek a collaboration. Whether we reach a definitive agreement for a collaboration will depend upon, among other things, our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of preclinical studies and clinical trials, the likelihood of approval by the FDA or other regulatory authorities, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing products, uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership without regard to the merits of the challenge), the terms of any existing collaboration agreements and industry and market conditions generally. The collaborator also may have the opportunity to collaborate on other drug candidates or technologies for similar indications and will have to evaluate whether such a collaboration could be more attractive than one with us. Collaborations are complex and time- consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical companies has reduced the number of potential future collaborators, and we may not be able to locate a suitable collaborator. Any collaboration we enter into may limit our ability to enter into future agreements on particular terms or covering similar target indications with other potential collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the drug candidate for which we are seeking to collaborate, reduce or delay its development program 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 increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate revenue from product sales, which could have an adverse effect on our business, financial condition, results of operations and prospects. We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for completing such trials. We rely on third- party contract research organizations (CROs) to conduct our Phase 1 clinical trial programs for NX- 5948, NX- 2127 and NX- 1607 and we will rely on third- party CROs to conduct any clinical trials for other drug candidates. Agreements with these CROs might terminate for a variety of reasons, including for such CRO' s failure to perform. Entry into alternative arrangements, if necessary, could significantly delay our product development activities. Our reliance on these CROs 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 in the applicable IND. Moreover, the FDA and other foreign regulators such as the EMA and the MHRA require compliance with good clinical practice standards, commonly referred to as 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. If these CROs 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 rely on third- party contract manufacturing organizations (CMOs) for the manufacture of both drug substance and finished drug product for our drug candidates for preclinical and clinical testing and expect to continue to do so for any future clinical trials and commercialization. This reliance on third parties may increase the risk that we will not have sufficient quantities of our drug candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on and expect to continue to rely on third- party contract manufacturing organizations (CMOs) for both drug substance and finished drug product. This reliance on CMOs, particularly where one CMO is the sole source of the drug substance or finished drug product, may increase the risk that we will not have sufficient quantities of our drug candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. **Further, we rely on third parties located in China for some of our contract manufacturing, and we expect to continue to use such third- party manufacturers for such purposes. For any activities conducted in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, new legislation or regulations, renegotiation of existing trade agreements, or any retaliatory trade actions due to recent**

or future trade tension, may impede, delay, limit, or increase the cost of manufacturing our therapeutic candidates. Such events could result in our clinical or commercial supply of drug, packaging and other services being interrupted or limited, which could harm our business. We may be unable to establish agreements with CMOs or to do so on acceptable terms. Even if we are able to establish agreements with CMOs, reliance on them entails additional risks, including: • reliance on the CMO for regulatory, compliance and quality assurance; • the possible breach of the manufacturing agreement by the CMO; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; and • the possible termination or nonrenewal of the agreement by the CMO at a time that is costly or inconvenient for us. We have only limited technology transfer agreements in place with respect to our drug candidates, and these arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long- term committed arrangements with respect to our drug candidates and other materials. If we receive marketing approval for any of our drug candidates, we will need to establish an agreement for commercial manufacture with a third party. The CMOs we retain may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions or other adverse regulatory actions, including untitled or warning letters, clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, failure to approve pending applications, license revocation, seizures or recalls of drug candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA or the EMA or other national or international regulatory agencies pursuant to inspections that will be conducted after we submit our new drug application (NDA) to the FDA or our MAA to the EMA or other regulatory authority. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA or comparable foreign regulatory bodies, they will not be able to secure and / or maintain approval for their manufacturing facilities. In addition, we do not have complete control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, the EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if such regulatory authority withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our drug candidates, if approved. Our drug candidates and any products that we may develop may compete with other drug candidates and products for access to suitable manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval or could result in withdrawal of marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current CMOs cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our drug candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or may not be able to reach agreement with any alternative manufacturer. Our current and anticipated future dependence upon others for the manufacture of our drug candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Some of our suppliers may experience disruption to their respective supply chain due to the effects of macroeconomic conditions, which could delay, prevent or impair our development or commercialization efforts. We obtain certain chemical or biological intermediates in the synthesis of our drug candidates and natural health products (NHPs) for toxicology testing in countries affected by macroeconomic events and conditions, including inflation, ~~increasing~~ interest ~~rates~~ **rate fluctuations**, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, increasing financial market volatility and uncertainty, the impact of war or military conflict, including regional conflicts around the world, and public health pandemics. If we are unable to obtain these chemical or biological intermediates or NHPs in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and clinical trials of that drug candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. Our CMOs may be unable to successfully scale- up manufacturing of our drug candidates in sufficient quality and quantity, which would delay or prevent us from developing our drug candidates and commercializing approved products, if any. In order to conduct clinical trials of our drug candidates, we will need to manufacture our drug candidates in large quantities. Quality issues may arise during scale- up activities. Our reliance on a limited number of CMOs, the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our drug candidates, cause us to incur higher costs and prevent us from commercializing our drug candidates successfully. Furthermore, if our CMOs fail to deliver the required commercial quality and quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement CMOs capable of production in a timely manner at a substantially equivalent cost, then testing and clinical trials of that drug candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. Risks Related to the Commercialization of Our Drug Candidates Even if any of our drug candidates receive marketing approval, a drug candidate 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 receive marketing approval,

they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. For example, ibrutinib is a well- established current treatment for chronic lymphocytic leukemia (CLL), and doctors may continue to rely on this and other treatments. If our drug candidates do not achieve an adequate level of acceptance, we may not generate sufficient revenue from product 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; • the prevalence and severity of any side effects, in particular compared to alternative treatments; • our ability to offer our products 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 our marketing, sales and distribution support; • the availability of third- party payor coverage and adequate reimbursement; • the ability to secure a positive HTA recommendation for the product to be prescribed and reimbursed under the national health system; • the timing of any marketing approval in relation to other product approvals; and • any restrictions on the use of our products together with other medications. If we are unable to establish sales and marketing capabilities, we may not be successful in commercializing our 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 biopharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish sales, marketing and distribution capabilities, either by ourselves or through collaboration or other arrangements with third parties. We currently expect that we may build our own focused, specialized sales and marketing organization to support the commercialization in the United States of drug candidates for which we receive marketing approval and which can be commercialized with such capabilities. There are risks involved with establishing our own sales and marketing 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 incurred these commercialization expenses prematurely or unnecessarily. These efforts 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 products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs and other support personnel; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we are unable to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services, our revenue from product sales and our profitability, if any, are likely to be lower than if we ourselves were to market and sell any products that we develop. In addition, we may not be successful in entering into arrangements with third parties to market and sell our drug candidates or may be unable to do so on terms that are acceptable to us. Any of these third parties may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Even if we are able to commercialize any drug candidates, the products may become subject to unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives, **or fail to secure a positive health technology assessment,** which would harm our business. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products 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 product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our drug candidate to other available therapies. In some ~~foreign~~ **non- U. S.** markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval. Our ability to commercialize any drug candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, national health technology assessment authorities in Europe and other organizations, and if reimbursement and coverage is available, the level of reimbursement and coverage. 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 key focus 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, as well as mandating a system of manufacturer rebates to government payors. Increasingly, government authorities and third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be sufficient to cover our costs. Reimbursement may affect the demand for, or the price of, any drug candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products 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 may not be able to successfully commercialize any drug candidate for which we obtain

marketing approval. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases, across the entire eligible patient population, as a first- line treatment or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, also may 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, may take into account comparative cost- effectiveness, particularly in European jurisdictions, 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. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our results of operations, our ability to raise capital needed to commercialize products and our overall financial condition. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our drug candidates or products 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 products that we may develop; • termination of clinical trials; • withdrawal of marketing approval, recall, restriction on the approval or a " black box " warning or contraindication for an approved drug; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards to trial participants or patients; • loss of revenue; • injury to our reputation and significant negative media attention; • reduced resources of our management to pursue our business strategy; and • the inability to commercialize any products that we may develop. Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our product liability insurance coverage as we initiate our clinical trials, as we expand our clinical trials and if we commence commercialization of our drug candidates. Insurance coverage is increasingly expensive. We may not be able to maintain or increase our insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Risks Related to Our Intellectual Property If we are unable to obtain and maintain patent protection for our technology, our current drug candidates and any future drug candidates that we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize technology and drug candidates similar or identical to ours, and our ability to successfully commercialize our technology and drug candidates may be impaired, and we may not be able to compete effectively in our market. Our commercial success depends, in large part, on our ability to obtain and maintain patent and other intellectual property and proprietary protection in the United States and other countries with respect to our current drug candidates, future drug candidates that we may develop and proprietary technology. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and drug candidates. If we are unable to obtain or maintain patent protection with respect to our proprietary drug candidates and technology or do not otherwise adequately protect our intellectual property, competitors and other third parties may be able to use our drug candidates and technologies and erode or negate any competitive advantage that we may have, which could have a material adverse effect on our business. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors and other third parties to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Moreover, the patent applications we own, co- own or license may fail to result in issued patents that cover our current and future drug candidates in the United States or in other foreign countries. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology. If the patent applications we hold with respect to our development programs and drug candidates fail to issue, if their breadth or strength of protection is threatened or if they fail to provide meaningful exclusivity for our current and future drug candidates, it could have a material adverse effect on our ability to commercialize our drug candidates and our business. To protect our proprietary positions, we file patent applications in the United States and other countries related to our novel technologies and drug candidates that are important to our business. The patent application and prosecution process is expensive, complex and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in all potential jurisdictions 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. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments, and it is possible that we may be unable to correct such defects. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors and other third parties may independently develop equivalent knowledge, methods and know- how, or design around our claimed subject matter. Any of these outcomes could impair our ability to prevent competition from third parties. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our therapeutics for

an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products " off- label. " Although off- label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. Consequently, the types of claims in issued patents of our patent portfolio may fail to afford strong protection against third- party infringement. 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, resulting in court decisions, including U. S. Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the protections offered by laws of different countries vary and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law and jurisprudence restricts the patentability of methods of treatment of the human body more than U. S. patent law does. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, whether owned or in- licensed, are highly uncertain. We may not be aware of all third- party intellectual property rights potentially relating to our current and future drug candidates or their intended uses, and as a result the impact of such third- party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions typically are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our patents or pending patent applications, or that we or our licensors were the first inventors 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, whether owned or in- licensed, may not result in patents being issued that protect our technology or drug candidates, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. 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. Moreover, we may be subject to third- party challenges in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third- party submissions of prior art to the United States Patent and Trademark Office (USPTO) challenging the validity of one or more claims of our owned or licensed pending patent applications, precluding the granting of a patent based on one of our owned or licensed pending patent applications or we may become involved in opposition, derivation, reexamination, inter partes review, post- grant review or other post- grant proceedings, in the United States or elsewhere, challenging our or our licensors' patent rights or the patent rights of others. An adverse determination in any such challenge could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights, which could significantly harm our business and results of operations. Such challenges may result in loss of patent rights or exclusivity, 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 technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Such proceedings also may result in substantial cost and require significant time from our scientific personnel and management, even if the eventual outcome is favorable to us. In addition, any threat to the breadth or strength of protection provided by our patents and patent applications 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 and are unchallenged, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors and other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors and other third parties may be able to design around or circumvent our patents, should they issue, by developing similar or alternative technologies or products in a non- infringing manner. Our competitors and other third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and / or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and / or unenforceable. If the patent protection provided by the patents and patent applications we own or license is not sufficiently broad and strong to impede such competition, our ability to successfully commercialize our drug candidates could be negatively affected and companies may be dissuaded from collaborating with us, which could have a material adverse effect on our business, financial condition, results of operations and prospects. 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 products similar or identical to ours. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Changes in patent law in the United States and in non- U. S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and

therefore is costly, time- consuming and inherently uncertain. Past or future patent reform legislation in the United States and other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, may diminish the value of our patents or narrow the scope of our patent protection and may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. Additionally, recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions and actions by the U. S. Congress, the U. S. Supreme Court, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Any of the foregoing, including any similar adverse changes in the patent laws of other jurisdictions, could also have a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are able to obtain patent protection for our drug candidates, the life of such protection is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights and our ability to successfully commercialize any product or technology would be materially adversely affected. The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would materially adversely affect any potential sales of that product. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a U. S. patent may also be shortened if the patent is terminally disclaimed over an earlier- filed patent. A patent term extension (~~"~~PTE ~~"~~) based on regulatory delay may be available in the United States **and in other jurisdictions, such as the UK and the EU, including through a supplementary protection certificate (SPC). In the EU and the UK, patent protection can be extended for a maximum period of five years and six months under certain circumstances** . However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Laws governing extensions analogous to PTEs in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our therapeutic will be shorter and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially. Upon the expiration of patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and other third parties, which would materially adversely affect our business, financial condition, results of operations and prospects. We may need to license intellectual property from third parties **that** ~~, such licenses~~ may not be available **to us** or may not be available on commercially reasonable terms **,** and we may not be successful in obtaining or maintaining necessary rights to our drug candidates through acquisitions and in- licenses. 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 the patented or proprietary technology of a third party to commercialize our own technology or drug candidates, in which case we would be required to obtain a license from such third party. Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license, or use these third- party proprietary rights. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may be unable to acquire or in- license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our drug candidates. The licensing and acquisition of third- party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, also may be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our drug candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional drug candidates we may seek to acquire. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate, which

could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business. Our commercial success depends, in part, upon our ability, and the ability of our collaborators to develop, manufacture, market and sell our drug candidates and future drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Numerous third- party U. S. and non- U. S. issued patents exist in the area of biotechnology, including in the area of targeted protein degraders and including patents owned or controlled by our competitors. There is considerable and complex intellectual property litigation in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination and inter partes review proceedings before the USPTO and oppositions and other comparable proceedings in foreign jurisdictions. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates, future drug candidates and technology, including interference, derivation, reexamination or inter partes review proceedings before the USPTO. Our competitors or other third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future and claims may also come from competitors or other third parties against whom our own patent portfolio may have no deterrent effect. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. Other parties may allege that our drug candidates or the use of our technologies infringe patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current and future drug candidates, competitors or other third parties may claim that our technology infringes, misappropriates or otherwise violates their intellectual property rights. There are and may in the future be additional U. S. and foreign- issued patents and pending patent applications owned by third parties in the fields in which we are pursuing drug candidates. For example, we are aware of a patent owned by a third party with a claim that covers many potential targeted protein degraders. This patent may be alleged to cover one or more of our targeted protein degrader drug candidates, including our NX- 5948 and NX- 2127 drug candidates. While we believe that we have valid defenses against any assertion of such patent against us, such defenses may be unsuccessful. If we are unsuccessful and any of our targeted protein degrader drug candidates is found to infringe this patent, we could be required to obtain a license to such patent or forced to permanently cease developing, manufacturing, marketing and commercializing the infringing targeted protein degrader drug candidate. We may not be able to obtain any required license on commercially reasonable terms or at all, and even if we were able to obtain a license, it could be non- exclusive, thereby giving the licensor and other third parties the right to use the same technologies licensed to us, and it could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease developing, manufacturing, marketing and commercializing the drug candidate. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willingly infringed any such patent. Even if we were ultimately to prevail, any litigation could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Moreover, as the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others. There may be third- party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates or we may incorrectly conclude that a third- party patent is invalid, unenforceable or not infringed by our activities. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our drug candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Patent and other types of the intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found, or believe there is a risk we may be found, by a court of competent jurisdiction to infringe, misappropriate or otherwise violate a third party' s intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing our products and technology. In addition, we could be found liable for monetary damages, which could be significant, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from producing or commercializing our drug candidates or future drug candidates or force us to cease some of our business operations, which could materially harm our business. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure, including due to any additional or separate regulatory approval to which the redesigned products may be subject by regulatory authorities, and any redesigned products may be of inferior quality or performance. If we lose a foreign patent lawsuit alleging our infringement of a competitor' s patents, we could be prevented from marketing our therapeutics in one or more foreign countries and / or be required to pay monetary damages for infringement or royalties in order to continue marketing. Claims that we have misappropriated the confidential information, trade secrets or other intellectual property of third parties could have a similar negative impact on our business. Any of these outcomes would have a material adverse effect on our business. Further, we do not know which processes we will use for commercial manufacture of our future products, or which technologies owned or controlled by third parties may prove important or essential to those processes. Many companies have filed, and continue to file, patent applications related to novel protein ~~modulation~~ **degradation** therapies that target disease- causing proteins and many companies have filed and continue to file patent applications related to ACT. Some of these patent applications have already been allowed or issued and others may issue in the future. Because this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there likely will be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. If a

patent holder believes the manufacture, use, sale, offer for sale or importation of one of our drug candidates or future products infringes its patent, the patent holder may sue us even if we have licensed other patent protection for our technology. Moreover, we may face patent infringement claims from non- practicing entities that have no relevant product revenue and against whom our licensed patent portfolio may therefore have no deterrent effect. It is also possible that we have failed to identify all relevant third- party patents or applications. Patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. For example, we may incorrectly determine that our drug candidates are not covered by a third- party patent or may incorrectly predict whether a third- party' s pending application will issue with claims of relevant scope. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale, importation or use of a current or future drug candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our therapeutics. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Furthermore, because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be applications now pending that we are not aware of that may later result in issued patents that may be infringed by the manufacture, use, sale or importation of our drug candidates or future products. Additionally, pending patent applications that have been published can, subject to certain limitations, later be amended in a manner that could cover our technologies, our future products or the manufacture or use of our future products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. If we were to challenge the validity of an issued U. S. patent in court, such as an issued U. S. patent of potential relevance to some of our drug candidates or future drug candidates or manufacture or methods of use, we would need to overcome a statutory presumption of validity that attaches to every U. S. patent. This burden is a high one and in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent' s claims. Even if we believe third- party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity or enforceability by invalidating the claims of any such U. S. patent or finding that our drug candidates or technology did not infringe any such claims. We may choose to challenge the enforceability or validity of claims in a third party' s U. S. patent by requesting that the USPTO review the patent claims in an ex- parte re- exam, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party' s patent in patent opposition proceedings in the European Patent Office (EPO) or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our drug candidates or proprietary technologies. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may be time- consuming, cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities and ongoing business operations. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our future products or processes. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a 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. Unlike some of our larger competitors and other third parties, we may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. Uncertainties resulting from the litigation of patent litigation and other proceedings could delay our research and development efforts, adversely affect our ability to raise additional funds and could limit our ability to continue our operations. Any of the foregoing could have a material adverse effect on our business. We may be subject to claims by third parties asserting that we or our employees, consultants, contractors or advisors have misappropriated, wrongfully used or disclosed alleged trade secrets or other intellectual property, or claiming ownership of what we regard as our own intellectual property. We may hire and employ individuals who were previously employed at, or may have previously provided or may be currently providing consulting services to, universities as well as other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We have received confidential and proprietary information from collaborators, prospective licensees and other third parties. Although we try to ensure that our employees, consultants and advisors do not improperly use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise improperly used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s former employer. We also may in the future be subject to claims that we have caused such individual to breach the terms of his or her non- competition or non- solicitation agreement or from former employers or other third parties claiming to have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and if we fail in defending any such claims, in

addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful, litigation could result in substantial cost and reputational loss and distract our management and other employees from their regular responsibilities. In addition, although it is our policy to require our employees, consultants and contractors who may be involved in the **conception or** development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact **conceives or** develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, such 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. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such litigation or proceeding 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 technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technology and drug candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our drug candidates without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors, or other intellectual property, which could be expensive, time- consuming and unsuccessful. Competitors or other third parties may infringe our patents, the patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which, regardless of merit, can be expensive, time- consuming, unpredictable and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke those parties to assert counterclaims against us alleging that we infringe their patents or other intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensors 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 in question. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non- enablement or failure to claim patent- eligible subject matter. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post- grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our drug candidates or prevent third parties from competing with our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on our drug candidates. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party' s use of our future patented technology falls under the safe harbor to patent infringement under 35 U. S. C. § 271 (e) (1). An adverse result in any litigation or proceeding involving our patents or patent applications may put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we successfully assert our patents or other intellectual property rights, a court may not award remedies that sufficiently compensate us for our losses. For example, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. The impact of public announcements of the results of hearings related to such awards on the price of our common stock may be uncertain. If securities analysts or investors perceive such results to be negative, it could have a substantial adverse effect on the price of our common

stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors or other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel for significant periods of time during such litigation could outweigh any benefit we receive as a result of the proceedings. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in- license needed technology or other drug candidates, or enter into development partnerships that would help us bring our drug candidates to market. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and prospects. **During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing drug candidates, approved products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business** We may not be able to pursue or guarantee protection of our intellectual property rights in jurisdictions outside the United States. Patents are of national or regional effect. Filing, prosecuting and defending patents on drug candidates, research programs and technology in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain technology and drug candidates outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors or other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our drug candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, may not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our business, financial condition, results of operations and prospects could be materially and adversely affected. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. In Europe, beginning June 1, 2023, European applications and patents may be subject to the jurisdiction of the Unified Patent Court (UPC). Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is ~~no~~ **very little** precedent for the court, increasing the uncertainty of any litigation. As a single court system can invalidate a European patent, we, where applicable, may opt out of the UPC, and as such, each European patent would need to be challenged in each individual country. Obtaining and maintaining patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent offices, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and / or patent application are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of the patent and / or patent application. The USPTO and patent offices in various foreign countries require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application process and throughout the life of a granted patent. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits,

non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors or other third parties might be able to enter the market, which could have a material adverse effect on our business and competitive position. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our drug candidates or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business **, financial condition, results of operations, and prospects** . Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. If 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 some of our technology and drug candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, and confidentiality agreements to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third- party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Trade secrets can be difficult to protect. We seek to protect our trade secrets, proprietary technology and processes, 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, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems; however, such systems and security measures may be breached, and we may not have adequate remedies for any breach. We cannot guarantee that we have entered into such agreements with each party that may have or had access to our trade secrets or proprietary technology and processes and even in cases we have, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or used in an unauthorized manner by third parties. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Furthermore, 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 expensive, time- consuming and difficult to prove and the outcome is unpredictable. In addition, some courts inside and outside of the United States may be less willing or unwilling to protect trade secrets. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Moreover, our competitors or other third parties may independently develop knowledge, methods and know- how equivalent to our trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, 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 or other third parties, our competitive position would be harmed. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own or license now or in the future, or may develop drug candidates for the diseases our drug candidates seek to treat that do not infringe on our intellectual property rights, but which perform better or are more successful than our drug candidates; • drug candidates utilizing issued patents and other intellectual property that we hold may prove to be ineffective for their intended treatment or we may not obtain regulatory approval for such drug candidates; • we, or our current or future license partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license now or in the future; • we, or our current or future license partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights; • it is possible that our pending owned patent applications or those that we may own or license in the future will not lead to issued patents; • we cannot predict the scope of protection of any patent issuing based on our

patent applications, including whether the patent applications that we own will result in issued patents with claims directed to our drug candidates or uses thereof in the United States or in other foreign countries; • the claims of any current patents or patent issuing based on patent applications that we own may not provide protection against competitors or any competitive advantages or may be challenged by third parties; • issued patents that we may hold rights to in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; • countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing drug candidates; • we may need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; • if we enforce and / or defend our patent rights, a court may not hold that our patents are valid, enforceable and infringed; • we may choose not to file a patent application in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent application covering such intellectual property; • we may fail to adequately protect and police our trademarks and trade secrets; and • the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving subject matter that is covered by our patent applications. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects. Risks Related to Regulatory Approval and Marketing of Our Drug Candidates The regulatory approval process of the FDA and other national or European regulators is lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our drug candidates, our business will be substantially harmed. The time required to obtain approval by the FDA and other national or European regulators is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate' s clinical development and may vary among jurisdictions. We have not obtained marketing approval for any drug candidate, and it is possible that none of our existing drug candidates, or any drug candidates we may seek to develop in the future, will ever obtain marketing approval. Our drug candidates could be delayed or fail to receive marketing approval for many reasons, including the following: • the FDA may disagree with our interpretation of data from preclinical studies or clinical trials; • the FDA may disagree with the design or implementation of our planned clinical trials; • data collected from clinical trials of our drug candidates may not be sufficient to support the submission of an NDA to the FDA or other submissions necessary to obtain marketing approval in the United States; • we may be unable to demonstrate to the satisfaction of the FDA that a drug candidate is safe and effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA for approval; • we may be unable to demonstrate that our drug candidates' clinical and other benefits outweigh their safety risks; • the FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA may significantly change **, including** in a manner rendering our clinical data insufficient for approval **or otherwise impacting the FDA' s review process and timing or requirements** . This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market any of our drug candidates, which would significantly harm our business, results of operations, financial condition and prospects. The FDA has substantial discretion in the approval process, and in determining when or whether regulatory approval will be obtained for any of our drug candidates. Even if we believe the data collected from clinical trials of our drug candidates are promising, such data may not be sufficient to support approval by the FDA. In addition, even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, or they may impose significant limitations in the form of narrow indications, warnings or a risk evaluation and mitigation strategy (REMS). In addition, regulatory authorities may not approve the price we intend to charge for our products, may require precautions or contra- indications with respect to conditions of use, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates. We have received Fast Track designation for NX- 5948 and may seek Fast Track designation for other drug candidates in the future. Fast Track designation may not lead to faster development or regulatory review or approval process, and it does not increase the likelihood that our drug candidates will receive marketing approval. In January 2024, the FDA granted Fast Track designation for NX- 5948 in the United States for the treatment of adult patients with relapsed or refractory CLL or small lymphocytic lymphoma after at least two lines of therapy, including a BTK inhibitory and a B- cell lymphoma 2 inhibitor **, and in December 2024, the FDA granted Fast Track designation for NX- 5948 in the United States for the treatment of adult patients with relapsed or refractory Waldenstrom' s macroglobulinemia after at least two lines of therapy, including a BTK inhibitor** . As part of our business strategy, we may also seek Fast Track designation for other of our drug candidates. Programs with Fast Track designation may be eligible for more frequent interactions with the FDA, and, if relevant criteria are met, eligibility for Accelerated Approval and Priority Review. Fast Track designation applies to the drug candidate and the specific indication for which it is being studied. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular drug candidate is eligible for this designation, we cannot guarantee that the FDA would decide to grant it. If a drug candidate receives Fast Track designation but does not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended

or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. The receipt of Fast Track designation for a drug candidate may not result in a faster development, regulatory review or approval process compared to drug candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any drug candidate qualifies for ~~FastTrack~~ **Fast Track** designation, the FDA may later decide that the drug candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Fast Track designation alone does not guarantee qualification for FDA Priority Review. Under FDA policies, a drug candidate is eligible for Priority Review, or review within a six- month time frame from the time a complete NDA is accepted for filing, if the drug candidate provides a significant improvement **in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions** compared to **available therapies** ~~marketed drugs in the treatment, diagnosis or prevention of a disease~~ . The FDA determines whether a drug qualifies for Priority Review after an NDA for such drug is submitted to the FDA. Therefore, until we submit NDAs for our drug candidates, we cannot be assured that they will be granted Priority Review. Even if Priority Review is granted for one of our drug candidates, the FDA does not always meet its six- month goal date for Priority Review, and the review process may be extended if the FDA requests additional information or clarification. We may submit an NDA for our drug candidates under the Accelerated Approval pathway. If we are unable to obtain approval of our drug candidates through the Accelerated Approval Program in the United States, we may be required to conduct additional nonclinical and clinical studies and trials beyond those that we currently contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and / or delay the timing of obtaining, necessary marketing approval. Even if we receive approval from the FDA through the Accelerated Approval Program, if our confirmatory postmarketing trial does not verify clinical benefit, or if we do not comply with rigorous postmarketing requirements, the FDA may seek to withdraw the approval. We may submit an NDA for one or more of our drug candidates seeking approval through the Accelerated Approval Pathway. For any approval to market a drug product, we must provide the FDA and foreign regulatory agencies with clinical data that adequately demonstrate the safety and efficacy of the product for the indication applied for in the NDA or other respective regulatory filings. The Accelerated Approval Program is one of several approaches used by the FDA to make prescription drugs more rapidly available for the treatment of serious or life- threatening diseases. Section 506 (c) of the Federal Food, Drug and Cosmetic Act (FDCA) provides that the FDA may grant Accelerated Approval to " a product for a serious or life- threatening condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. " Approval through the Accelerated Approval Program is subject, however, to the requirement that the applicant conduct additional postmarketing clinical trials to verify and describe the drug' s clinical benefit, where there is uncertainty as to the relationship of the surrogate endpoint to the clinical benefit, or of the observed clinical endpoint to ultimate outcome. Typically, clinical benefit is verified when postmarketing clinical trials show that the drug provides a clinically meaningful positive therapeutic effect, that is, an effect on how a patient feels, functions, or survives. The FDA may require that these studies be underway prior to Accelerated Approval pursuant to the Food and Drug Omnibus Reform Act of 2022 **and under the FDA' s draft guidance on " Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway " made available in January 2025** . If such confirmatory trials fail to confirm the drug' s clinical profile or risks and benefits, the FDA may withdraw its approval of the drug. The FDA has broad discretion with regard to approval through the Accelerated Approval Program, and even if we believe that the Accelerated Approval Program is appropriate for one of our drug candidates, we cannot assure you that the FDA will ultimately agree. The FDA may also change its policies with respect to Accelerated Approval over time. For example, in March 2023, the FDA announced the availability of draft guidance on " Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics, " in which the agency outlined, and invited public comment on, its " preferred approach " of randomized controlled trials, including those that provide for longer term follow- up that could fulfill a postmarketing requirement to verify clinical benefit. In that draft guidance, the FDA acknowledged that historically, single- arm trial designs and response endpoints have most commonly been used in oncology but noted that such trials have limitations. Furthermore, even if we do obtain approval through the Accelerated Approval Program, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Even if the FDA reviews an NDA seeking Accelerated Approval, there can be no assurance that approval will be granted on a timely basis, or at all. The FDA may disagree that the design of, or results from, our studies support Accelerated Approval. Additionally, the FDA could require us to conduct further studies or trials prior to granting approval of any type, including by determining that approval through the Accelerated Approval Program is not appropriate and that our clinical trials may not be used to support approval through the conventional pathway. We might not be able to fulfill the FDA' s requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. There also can be no assurance that after subsequent FDA feedback we will continue to pursue approval through the Accelerated Approval Program. A failure to obtain approval through the Accelerated Approval Program could result in a longer time period to obtain approval of our drug candidates, could increase the cost of their development, could delay our ability to commercialize our products and could significantly harm our financial position and competitive position in the marketplace. Even if we receive approval for one or more of our drug candidates through the Accelerated Approval Program, we will be subject to rigorous postmarketing requirements, including the completion of one or more confirmatory postmarketing trials as the FDA may require, to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw the approval for multiple reasons, including if we fail to conduct any required confirmatory postmarketing trial with due diligence, our confirmatory postmarketing trial does not confirm the predicted clinical benefit, other

evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading. Moreover, Congress is considering potential changes to the Accelerated Approval Program that could impact our ability to obtain Accelerated Approval, or increase the burdens associated with postmarketing requirements in the event we do obtain Accelerated Approval. In particular, the FDA must specify certain conditions for required postapproval studies for products that receive Accelerated Approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the drug is approved. The FDA may also require postapproval studies to be underway at the time of Accelerated Approval or within a specified time period following Accelerated Approval for such drugs, and must explain any instances where it does not require such studies. **The FDA' s January 2025 draft guidance on " Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway, " while not finalized, suggests that the FDA generally intends to consider a confirmatory trial to be " underway " prior to accelerated approval if (1) the trial has a target completion date that is consistent with diligent and timely conduct of the trial, considering the nature of the trial' s design and objectives, (2) the sponsor' s progress and plans for postapproval conduct of the trial provide sufficient assurance to expect timely completion of the trial, and (3) enrollment of the confirmatory trial has been initiated.** Any delay in obtaining, or inability to obtain, approval through the Accelerated Approval Program, or any issues in maintaining approval granted under the Accelerated Approval Program, would delay or prevent commercialization of our products, and would materially adversely affect our business, financial condition, results of operations and prospects. We, as a company, have limited experience in filing for and obtaining regulatory approval to initiate a clinical trial, and we do not have experience completing any clinical trials, including large- scale, pivotal clinical trials or in manufacturing or in quality assurance in order to market a new drug in the United States or in any other jurisdiction. As a company, we have limited experience in filing for or obtaining regulatory approval to initiate clinical trials, we do not have experience completing any clinical trials, including large- scale, pivotal clinical trials and we rely on third parties to conduct our clinical trials. We also do not have experience in manufacturing or in quality assurance in order to market a new drug and expect to rely on CROs or other third- party consultants or vendors to assist us in this process. Our inexperience may result in failure to or delays in obtaining the required regulatory approvals to initiate clinical trials, to successfully complete clinical trials and to obtain marketing approval for our drug candidates. If we are unable to obtain regulatory and marketing approval for our drug candidates or experience significant delays in our efforts to do so, our business could be substantially harmed. Failure to obtain marketing approval in foreign jurisdictions would prevent our drug candidates from being marketed abroad and may limit our ability to generate revenue from product sales. To market and sell our drug candidates in jurisdictions outside the United States, we 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 approvals from foreign regulatory authorities 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, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Failure to obtain foreign regulatory approvals on a timely basis or non- compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our drug candidates in certain countries. 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 countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any jurisdiction, which would materially impair our ability to generate revenue. The UK' s exit from the EU continues to create political and economic uncertainty, particularly in the UK and the EU. The UK is now being treated as a " third country " by the EU. Although UK legislation has retained existing EU law, new UK legislation is being drafted and the UK has not retained new EU law, including the Clinical Trials Regulation (EU) No 536 / 2014. This means that some regulatory activities, such as batch testing and Qualified Person certification, conducted in the UK are no longer recognized in the EU; although the UK accepts the batch testing data carried out in many third countries with recognized equivalent high standards to avoid delays and supply disruption due to re- testing. However, the UK and EU have concluded a Trade and Cooperation Agreement (TCA), which has been approved by the UK Parliament, European Council and European Parliament and has limited the disruption to the supply of medicines, particularly by enabling tariff and quota- free trade between the UK and the EU (provided that the rules of origin requirements are met), and has streamlined some issues, for example by enabling mutual recognition of cGMP inspections and certificates. The regulatory framework for medicines that existed before the end of the transition period has also effectively been preserved in UK domestic legislation as " retained EU law. " By retaining a snapshot of EU legislation at its core, the UK has prevented substantial divergence in the regulation of medicines (although divergence has appeared in some areas). However, some changes to the UK legislation have been immediately necessary, including the implementation of the Northern Ireland Protocol (NIP), pursuant to which, the EU pharmaceutical legal framework acquis continues to apply in Northern Ireland (subject to periodic consent of the Northern Ireland Legislative Assembly), and only products compliant with EU law can be placed in the Northern Ireland market — adding an extra layer of regulatory complexity. As a result, companies now need to comply with a separate UK regulatory legal framework in order to commercialize medicinal products in Great Britain (namely, England, Wales and Scotland, as EU law continues to apply in Northern Ireland). The UK government has attempted to renegotiate fundamental aspects of the NIP so this is an unpredictable area for companies in the near future. Failed attempts to renegotiate the NIP have led to media reports of the UK potentially triggering Article 16 of the NIP, a safeguarding measure, that may be engaged unilaterally if the application of the NIP leads to serious economic, societal or environmental difficulties that are liable to persist, or to diversion of trade. The UK government has introduced the Northern Ireland Protocol Bill which, if enacted into law, would enable the government to unilaterally disapply parts of the NIP which may lead to changes to the regulatory environment in Northern Ireland, and may

trigger retaliatory measures against the UK by the EU. The UK government reached a new agreement with the EU, the " Windsor Framework, " which aims to ~~replace~~ **amend** the NIP. According to the Windsor Framework, medicinal products intended for the UK market including Northern Ireland will be authorized by the MHRA and will bear a " UK only " label. This means that medicinal products placed on the market in Northern Ireland will no longer need to be compliant with EU law. These new measures will be implemented beginning January 1, 2025. The TCA allows for future deviation from the current regulatory framework, and it is not known if and / or when any deviations may occur, which may have an impact on development, manufacture, marketing authorization, commercial sales and distribution of pharmaceutical products. It is also important to note that obtaining a marketing authorization is not sufficient to gain effective access to the market in the EU and in the UK; companies still need to agree to a reimbursement price for the products and in some jurisdictions, such as the UK and Germany, a further positive recommendation from health technology on cost- effectiveness is required for the products to be actually prescribed and reimbursed by the respective national health systems (see " — Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues from the sales of drugs, if any " below). If we fail to comply with the regulatory requirements in international markets and thus do not receive applicable marketing approvals, our target market will be reduced, our ability to realize the full market potential of our drug candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, or at all. Our failure to obtain approval of any of our drug candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that drug candidate and our business prospects could decline. Even if we, or any collaborators, obtain marketing approvals for our drug candidates, the terms of approvals and ongoing regulation of our products may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue. Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators, must therefore comply with requirements concerning advertising and promotion for any of our drug candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved labeling. Thus, we, and any collaborators, will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA, EMA, MHRA and other regulatory requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation and reporting requirements. We, our third- party manufacturers, and any collaborators and their third- party manufacturers could be subject to periodic unannounced inspections by the FDA and other regulatory agencies to monitor and ensure compliance with cGMPs. Accordingly, assuming we, or any collaborators, receive marketing approval for one or more of our drug candidates, we, any collaborators, and our respective third- party manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and any collaborators, are not able to comply with post- approval regulatory requirements, we, and any collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or any collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post- approval regulations may have a negative effect on our business, results of operations, financial condition and prospects. Any drug candidate for which we, or any collaborators, obtain marketing approval could be subject to post- marketing restrictions or withdrawal from the market and we, or any collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products when and if any of them are approved. Any drug candidate for which we, or any collaborators, obtain marketing approval, as well as the manufacturing processes, post- approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA, EMA, the MHRA 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, tracking and tracing, serialization, postmarket adverse event reporting and recordkeeping. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement REMS. New cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed. If any of our drug candidates receive marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product. Clinical trials of our drug candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a drug candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our drug candidates receives marketing approval and we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw their approval of the drug or seize the drug; • we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials; • additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug; • we may be subject to fines, injunctions or the imposition of civil or criminal penalties; • regulatory authorities may require the addition of labeling statements, such as a " black box " warning or a contraindication; • we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients; • we, or any future collaborators, could be sued and held liable for harm caused to patients; • the drug

may become less competitive in the marketplace; and • our reputation may suffer. Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price. The FDA also may impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of REMS. The FDA and other agencies, including the U. S. Department of Justice (DOJ), closely regulate and monitor the post- approval marketing and promotion of drugs to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off- label use, and if we do not market our products only for their approved indications, we may be subject to enforcement action for off- label marketing. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. Other jurisdictions, including European countries, have similar provisions which may lead to investigations and enforcement actions by national authorities. In addition, later discovery of previously unknown side effects or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: • restrictions on such products, manufacturers or manufacturing processes; • restrictions and warnings on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning letters or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • suspension of any ongoing clinical trials; • damage to relationships with any potential collaborators; • unfavorable press coverage and damage to our reputation; • refusal to permit the import or export of our products; • product seizure; • injunctions or the imposition of civil or criminal penalties; or • litigation involving patients using our products. Non- compliance with EU and UK requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population (as explained further under " — If any of our drug candidates are not considered to be a new active substance or are deemed to fall within the " global marketing authorization " of an existing medicinal product or if pediatric studies are not adequately completed, this may result in lack of regulatory data protection or failure to obtain an extension to existing regulatory data protection, " below), also can result in significant financial penalties, and non- compliance with pediatric requirements may prevent regulatory approvals from being granted. Similarly, failure to comply with the EU and UK' s requirements regarding the protection of personal information can lead to significant penalties and sanctions. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our collaborators and their contract manufacturers also will be subject to other regulatory requirements, including submissions of safety and other post- marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, such as the requirement to implement a REMS. If we decide to seek Orphan Drug Designation or other designations from regulators for any of our current or future drug candidates, we may be unsuccessful or may be unable to maintain the benefits associated with these designations, including the potential for supplemental market exclusivity associated with an Orphan Drug Designation. We may seek Orphan Drug Designation or other designations from regulators for one or more of our current or future drug candidates. Regulatory authorities in some jurisdictions, including the United States, EU and European Economic Area (EEA), Switzerland and the UK, may designate drugs or biological products for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug or biological product. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. After the FDA grants Orphan Drug Designation, the identity of the drug or biological product and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review process. If a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA or BLA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the biological product was designated. As a result, even if one of our drug candidates receives orphan exclusivity, the FDA can still approve or license other drugs or biological products for use in treating the same indication or disease. Further, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product. In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a ~~recent~~ **2021** decision by the U. S. Court of Appeals for the Eleventh Circuit. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, results of operations, financial condition and prospects. We may seek Orphan Drug Designation for our drug candidates in additional orphan indications in which there is a medically plausible basis for the use of these drug candidates. Even when we obtain Orphan Drug Designation,

exclusive marketing rights in the United States may be limited if we seek licensure for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we, through our manufacturer, are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we may seek Orphan Drug Designation for other drug candidates, we may never receive these designations. In order to obtain orphan designation in the EEA (the UK has a similar legislation), the product must fulfill certain criteria. Under Article 3 of Regulation (EC) 141 / 2000, a medicinal product may be designated as an orphan medicinal product if it meets the following criteria: (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either the prevalence of such condition must not be more than five in 10, 000 persons in the EU when the application is made, or without the benefits derived from orphan status, it must be unlikely that the marketing of the medicine would generate sufficient return in the EU to justify the investment needed for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847 / 2000. Products receiving orphan designation in the EU may receive 10 years of orphan market exclusivity (which can be further extended by two years if pediatric studies have been conducted in accordance with an agreed pediatric investigational plan). Applications must first satisfy the orphan designation criteria and apply for orphan designation before making the application for marketing authorization. The applicant must then successfully maintain the orphan designation at the time of the MAA in order to qualify for 10 years of orphan market exclusivity. During this 10- year period, the competent authorities of the EU Member States and European Commission may not accept applications or grant marketing authorization for other similar medicinal products for the same orphan therapeutic indication. The protection afforded by orphan market exclusivity in the EU may, in some circumstances, be circumvented by competitor products which are demonstrated not to be " similar " or which are authorized for different therapeutic indications. There may be a risk that products may be prescribed " off-label " for the orphan therapeutic indication by healthcare professions in some EU Member States. There are also three exceptions to the orphan market exclusivity principle. Marketing authorization may be granted to a similar medicinal product for the same orphan therapeutic indication if: • the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior; • the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or • the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product. An orphan product can also obtain an additional two years of orphan market exclusivity in the EU if the MAA contains the results of all pediatric studies conducted in accordance with and agreed pediatric investigation plan. The 10- year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation; for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. The UK' s regulatory legal framework provides for similar periods of protection (namely regulatory data protection, marketing protection and market exclusivity). It is important to note that the regulatory protection afforded to medicinal products such as data exclusivity, marketing protection, market exclusivity for orphan indications and pediatric extension are currently under review at the EU level. It is expected that the protection currently afforded in the EU will be reduced in the years to come. On April 26, 2023, the European Commission adopted a proposal for a new Directive and a new Regulation. If enacted into law, this proposal will revise and replace the existing general pharmaceutical legislation and will affect the existing period of regulatory protections afforded to medicinal products **. The proposal is now undergoing the legislative process and the text of the initial proposal is likely to be amended by the European Parliament and the European Council** . If the FDA or comparable foreign regulatory authorities approve generic versions of any of our drug candidates that receive marketing approval, or such authorities do not grant our drug candidates appropriate periods of data or market exclusivity before approving generic versions of our drug candidates, the sales of our drug candidates could be adversely affected. Once an NDA is approved, the drug covered thereby becomes a " reference- listed drug " in the FDA' s publication, " Approved Drug Products with Therapeutic Equivalence Evaluations. " Manufacturers may seek marketing approval of generic versions of reference- listed drugs through submission of abbreviated new drug applications (ANDAs) in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials demonstrating safety and efficacy. Rather, the applicant generally must show that its drug is pharmaceutically equivalent to the reference listed drug, in that it has the same active ingredient (s), dosage form, strength, route of administration and conditions of use or labeling as the reference- listed drug, and that the generic version is bioequivalent to the reference- listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic drugs may be significantly less costly to bring to market than the reference- listed drug and companies that produce generic drugs are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference- listed drug is typically lost to the generic drug. The FDA may not approve an ANDA for a generic drug until any applicable period of non-patent exclusivity for the reference- listed drug has expired. The FDCA provides a period of five years of non- patent exclusivity for a new drug containing a new chemical entity. During the exclusivity period, the FDA may not accept for review an ANDA or a 505 (b) (2) NDA submitted by another company for another version of such drug candidate where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non- infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505 (b) (2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug candidate. This three- year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drug candidates containing the original active agent for other conditions of use. Five- year and three-

year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well- controlled clinical trials necessary to demonstrate safety and effectiveness. Manufacturers may seek to launch these generic drugs following the expiration of the marketing exclusivity period, even if we still have patent protection for our drug. Competition that our drug candidates may face from generic versions of our drug candidates could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those drug candidates. Our future revenues, profitability and cash flows could also be materially and adversely affected and our ability to obtain a return on the investments we have made in those drug candidates may be substantially limited if our drug candidates, if and when approved, are not afforded the appropriate periods of non- patent exclusivity. If any of our drug candidates are not considered to be a new active substance or are deemed to fall within the " global marketing authorization " of an existing medicinal product or if pediatric studies are not adequately completed, ~~this~~ **such drug candidates** may **fail to obtain** ~~result in lack of~~ regulatory data protection or ~~failure to obtain~~ an extension to existing regulatory data protection. Where an applicant for a marketing authorization submits a full dossier containing its own pharmaceutical, preclinical tests and clinical trials data, and where the application does not fall within the " global marketing authorization " of an existing medicinal product, the applicant is entitled to eight years of regulatory data protection upon grant of the marketing authorization (the period starts to run from the first marketing authorization in the EU and EEA). During this period, applicants for approval of generics or biosimilars cannot rely on data contained in the marketing authorization dossier submitted for the already authorized, or reference, medicinal product to support their application. After the expiration of the eight- year period of regulatory data protection, the reference medicinal product benefits from a further two- year period of marketing protection. During these two years of marketing protection, no generic or biosimilar medicinal product that relies upon the reference medicinal product' s dossier may be placed on the EU market, but a generic or biosimilar MAA can be submitted to the competent regulatory authorities in the EU Member States during this time. The two- year period of marketing protection can further be extended by one year if, during the first eight years of the grant of the first marketing authorization, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, even if a compound is considered to be a new active substance and the innovator is able to gain the period of regulatory data protection and marketing protection, provided that no other IP or regulatory exclusivities applied, another unrelated company could also apply for a marketing authorization and market another competing medicinal product for the same therapeutic indication if such company obtained its own marketing authorization based on a separate MAA based on a full self- standing scientific data package supporting the application. The period of regulatory data protection and marketing protection applies in the UK (running from the date of the first authorization in Great Britain). In the EU, pursuant to Regulation 1901 / 2006, and in the UK pursuant to the Human Medicines Regulations 2012 (as amended), MAAs must include pediatric data based on pediatric investigation plans agreed with the EMA if the MAA concerns (i) a new active substance, or (ii) a new indication, pharmacological form, or route of administration (where the product is protected by **an SPC** ~~a supplementary protection certificate~~ or a patent qualifying for **an SPC** ~~a supplementary certificate~~). Applicants may obtain waivers or deferrals to these requirements in certain circumstances (for example a waiver may be obtained if the condition only occurs in adult populations). Where required, pediatric studies must cover all sub- sets of the pediatric population for both existing and new indications, pharmacological forms and route of administrations. Limited further exclusions apply, including in relation to generic or biosimilar applications. Certain rewards may be available for completion of pediatric studies. For example, where MAAs include the results of all studies conducted in compliance with an agreed pediatric investigation plan, the holder of the patent or **SPC** ~~supplementary protection certificate~~ may be entitled to a six- month extension to the **SPC** ~~supplementary protection certificate~~ . Additionally, the European Commission' s new proposed legislation, if implemented, will also affect the current EU legal framework of pediatric medicines. Our operations and relationships with actual and potential customers, providers and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, exclusions from government programs, contractual damages and reputational harm, and could diminish our future profits and earnings. Our arrangements with third- party payors, physicians, and other potential customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drug candidates for which we obtain marketing approval. Applicable U. S. federal and state and non- U. S. healthcare laws and regulations include the following: • the federal Anti- Kickback Statute, a criminal law, which prohibits, among other things, persons and entities from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, to induce or reward purchasing, leasing, ordering, or arranging for, referring, or recommending the purchase, lease or order of any good or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the federal Anti- Kickback Statute can result in significant civil monetary penalties and criminal fines, as well as imprisonment and exclusion from participation in federal healthcare programs; • the federal Civil False Claims Act, which may be enforced through civil whistleblower or qui tam actions and imposes significant civil penalties, treble damages and potential exclusion from federal healthcare programs against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or for making a false record or statement material to an obligation to pay the federal government or for knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Further, a violation of the federal Anti-Kickback Statute can serve as a basis for liability under the federal ~~Civil~~ **civil** False Claims Act. There is also the federal ~~Criminal~~ **criminal** False Claims Act, which is similar to the federal ~~Civil~~ **civil** False Claims Act and imposes criminal liability

on those that make or present a false, fictitious or fraudulent claim to the federal government; • the federal ~~Civil~~ **civil** Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal ~~health~~ **healthcare** ~~care~~ programs to provide items or services reimbursable by a federal ~~health~~ **healthcare** ~~care~~ program; (3) violations of the federal Anti- Kickback Statute; or (4) failing to report and return a known overpayment; • federal criminal statutes created by the Health Insurance Portability and Accountability Act (HIPAA), which impose criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private insurance plans, or, in any matter involving a healthcare benefit program, for knowingly and willfully making materially false, fictitious or fraudulent statements in connection with the delivery of or payment for ~~health~~ **healthcare** ~~care~~ benefits; • HIPAA, as amended by the Health Information Technology for Economic Clinical Health Act, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the federal Food, Drug, and Cosmetic Act and Public Health Service Act which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off- label use or misbranding or adulterating their products, and regulates the distribution of samples; • the federal and state laws that require pharmaceutical manufacturers to report certain calculated product pricing metrics to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of product coverage and reimbursement under federal healthcare programs; • the federal Physician Payment Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, among others, to annually track and report payments and other transfers of value provided to U. S.- licensed physicians, teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse- midwives, as well as certain ownership and investment interests held in the manufacturer by physicians and their immediate families; • analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to our business practices, including sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; • state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and relevant compliance guidance promulgated by the federal government; • state 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 that prohibit various marketing- related activities, such as the provision of certain kinds of gifts or meals; require the reporting of certain pricing information, including information pertaining to and justifying price increases, or prohibit prescription drug price gouging; impose payment caps on certain pharmaceutical products deemed by the state to be " high cost "; and require the registration of pharmaceutical sales representatives; and • state and foreign laws that govern the privacy and security of health information in some 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 will 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, damages, fines, imprisonment, exclusion of drug candidates from government- funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may also be subject to criminal, civil or administrative sanctions, including exclusions from government- funded healthcare programs. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause us to incur significant legal expenses and divert management' s attention from the operation of the business, even if such action is successfully defended. Providing benefits or advantages to induce or reward improper performance generally to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU and the UK. The provision of benefits or advantages to induce or reward improper performance is governed by the national anti-bribery laws of EU Member States, and ~~in~~ **with** respect ~~of~~ **to** the UK, the UK Bribery Act 2010 (Bribery Act). Infringement of these laws may result in substantial fines and imprisonment. EU Directive 2001 / 83 / EC, which is the EU Directive governing medicinal products for human use, provides that, where medicinal products are being promoted to healthcare professionals, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such individuals unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision was transposed into the Human Medicines Regulations 2012 and as such remains applicable in the UK. Payments made to physicians in certain EU Member States must be publicly disclosed. In addition, agreements with healthcare professionals must often be the subject of prior notification and approval by the healthcare professional' s employer, his or her competent professional organization and / or the regulatory authorities of individual EU Member States. These requirements are set out in national laws, industry codes or professional codes of conduct, applicable in the EU Member States and in the UK. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. The FDA' s and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. The FDA' s and other regulatory authorities' policies may change, and additional

government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation **, judicial** or administrative or executive action, either in the United States or abroad. Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay 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. The biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA- approved product. Healthcare reform measures that may be adopted in the future may result in reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and / or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. To date, there have been several U. S. congressional inquiries and proposed and enacted state and federal legislation and regulations designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient support programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. Most notably, the Inflation Reduction Act (IRA), which was signed into law on August 16, 2022, allows Medicare to: beginning in 2026, establish a " maximum fair price " for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the Centers for Medicare and Medicaid Services (CMS); and, beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation, among other reforms. **The** CMS has ~~recently~~ taken **a number of** steps to implement the IRA, including: **on August 29** ~~• On June 30~~ , 2023, **releasing** ~~issuing guidance detailing~~ the **initial list** ~~requirements and parameters~~ of ~~the first round of~~ **ten drugs subject to** price negotiations **; on August 15** , ~~to take place during 2023 and~~ 2024 **releasing the negotiated maximum prices for such drugs that will be effective beginning in 2026; on October 2** , **2024, releasing final guidance outlining the process for the second round of price negotiations** for products subject to the " maximum fair price " provision ~~that would become effective in 2026~~ ; ~~• On August 29~~ **and on December 20** , ~~2023~~ **2024** , releasing **a** ~~the initial~~ list of **64** ~~10 drugs subject to price negotiations; • On November 17, 2023, releasing guidance outlining the methodology for identifying certain manufacturers eligible to participate in a phase- in period where discounts on applicable products will be lower than those required by the Medicare Part D Manufacturer Discount Program; and • On December 14, 2023, releasing a list of 48~~ Medicare Part B products that had **an** adjusted coinsurance ~~rates~~ **rate** based on the inflationary rebate provisions of the IRA for the time period of January 1, ~~2024~~ **2025** to March 31, ~~2024~~ **2025** ~~as well as issuing revised guidance for manufacturers in the Medicare Part B and D drug discount programs~~ . It is unclear how future regulatory actions to implement the IRA, as well as the outcome of pending litigation against the IRA, may affect our products and future profitability ~~. On October 14~~ , **and we cannot predict the likelihood, nature, or extent of other health reform initiatives that may arise from future legislation or administrative actions. Moreover, the results of the** ~~2022~~ **2024** ~~, President~~ **Presidential** ~~Biden~~ **and Congressional elections, and potential subsequent developments, increase the uncertainty related to the healthcare regulatory environment. In addition, on June 28, 2024, the U. S. Supreme Court** issued an **opinion holding** ~~Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of the Department of Health and Human Services (HHS) to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models~~ that ~~would lower drug costs~~ **courts reviewing agency action pursuant to the APA " must exercise their independent judgment " and " may not defer to** ~~and~~ **an agency interpretation of** ~~promote access to innovative drug therapies for beneficiaries enrolled in~~ the ~~Medicare and Medicaid programs~~ **law simply because a statute is ambiguous** . **"** The **decision** ~~Executive Order further directed the Secretary of HHS to submit, within 90 days after the date of the Executive Order, a report regarding any models that may lead to lower cost- sharing for commonly used drugs and support value- based payment that promotes high- quality care. On February 14, 2023, the HHS issued a report in response to the October 14, 2022 Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a " high- value drug list " setting the maximum co- payment amount for certain common generic drugs at $ 2; (2) a Medicaid- focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi- state outcomes- based agreements or certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments. We cannot be sure what impact, if any, the foregoing changes~~ will have **a significant impact** on **how lower courts evaluate challenges to agency interpretations of law, including** ~~the~~ **those by CMS and** ~~profitability of any of our drug candidates, if approved for commercial use, in the~~ **other** ~~future~~ **agencies with significant oversight of the healthcare industry** . **For additional information, see the risk factor above titled " The biopharmaceutical industry is subject to extensive regulatory obligations and policies that are subject to change, including due to judicial challenges. "** At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. These include legislation and regulations regarding price or patient

reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, legislative action designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida' s importation plan, which allows pharmacists and wholesalers to import certain products from Canada. In addition, regional ~~health~~ **healthcare** ~~care~~ authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other ~~health~~ **healthcare** ~~care~~ programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. Legislative and regulatory proposals have also been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. 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 of the United States tend to impose strict price controls, which may adversely affect our revenues from the sales of drugs, if any. In some countries, particularly the countries of the EU and the UK, 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 reimbursement or pricing approval in some countries, we, or our collaborators, may be required to conduct a clinical trial that compares the cost- effectiveness of our drug to other available therapies. Furthermore, in some European countries, the authorities conduct an HTA to assess the cost- effectiveness of the product (in the UK that HTA assessment is conducted by the National Institute for Health and Care Excellence), which may significantly impact effective access to the market. 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 materially harmed. Risks Related to Employees, Managing our Growth and Other Legal Matters If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop our current and any future drug candidates, commercialize our drug candidates or otherwise implement our business plan. Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including our President and Chief Executive Officer, Arthur T. Sands, M. D., Ph. D., and Chief Scientific Officer, Gwenn Hansen, Ph. D. The loss of the services of Dr. Sands, Dr. Hansen or other members of our senior leadership team could impede, delay or prevent the successful development of our product pipeline, completion of our current and planned clinical trials, commercialization of our products or in- licensing or acquisition of new assets, and could negatively impact our ability to successfully implement our business plan. If we lose the services of such individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at- will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options and restricted stock units (RSUs) that vest over time. The value to employees of stock options and RSUs that vest over time will be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies. Moreover, we might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are unable to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives. In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations. As our development and commercialization plans and strategies develop, and as we continue our transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development. We filed our first IND in December 2020 and currently have three drug candidates in ongoing Phase 1 trials **, and expect to advance our drug candidate NX- 5948 to a Phase 2 clinical trial in 2025** . As our drug candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects. Our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading laws. We are

exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include: • intentional, reckless or negligent conduct or disclosure to us of unauthorized activities that violate the regulations of the FDA or similar foreign regulatory authorities; • healthcare fraud and abuse in violation of U. S. and foreign laws and regulations; • violations of U. S. federal securities laws relating to trading in our common stock; and • failures to report financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations regulate a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. While we have adopted a code of conduct and implemented other internal controls applicable to all of our employees, it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective. Additionally, we are subject to the risk that a person could allege fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs and diminished profits and future earnings, any of which could adversely affect our ability to operate our business or cause reputational harm. We depend on our information technology systems, and any failure of these systems, or those of our CROs, third- party vendors, collaborators or other contractors or consultants we may utilize, could harm our business. Security breaches, cyber- attacks, loss of data and other disruptions could compromise sensitive information related to our business or other personal information, prevent us from accessing critical information and expose us to liability, which could adversely affect our business, reputation, results of operations, financial condition and prospects. We ~~collect and maintain information in digital form that is necessary to conduct our business, and we~~ are increasingly dependent on information technology systems, infrastructure and data to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential **and sensitive** information, including but not limited to intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such ~~confidential~~ information. We have established physical, electronic and organizational measures to safeguard and secure our systems which are designed to prevent data compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of ~~digital~~ **our** information. We have also outsourced elements of our information technology infrastructure, resulting in a number of third- party vendors that may or could have access to our ~~confidential~~ information. Despite the implementation of security measures, our internal information technology systems and infrastructure, and those of our current and any future CROs, collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to breach, breakdown or other damage or interruption from service interruptions, system malfunction, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber- attacks or cyber- intrusions over the Internet (including harmful attachments to emails, ransomware, **distributed** denial- of- service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), persons inside our organization, or persons with access to systems inside our organization. Any of the foregoing may compromise or lead to data leakage of our system infrastructure, or that of our CROs, third- party vendors and other contractors and consultants. The risk of a security breach or disruption, particularly through cyber- attacks or cyber- intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources. In addition, the prevalent use of mobile devices and remote work applications that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property or unauthorized access to personal information. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third- party vendors, CROs and other contractors and consultants, or inappropriate disclosure of confidential, personal or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our drug candidates could be delayed. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be material, and although we have and continue to invest in and implement security measures designed to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If the information technology systems of our third- party vendors, CROs and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. We and our third- party service providers regularly defend against and respond to data security incidents, and we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third- party vendors, CROs and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. If such an event were to occur that causes interruptions in our operations, or those of our third- party vendors, CROs and other contractors and consultants, it could result in a material disruption or delay of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Furthermore, significant disruptions of our internal information technology systems or those of our third- party vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation, and / or unauthorized access, use, or disclosure of, or the prevention of access to, confidential **or sensitive** information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. If any such event, including a ~~computer~~ security breach, results in the unauthorized access, use or release of personal information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state data privacy and security laws (and other similar **international** ~~non- U. S.~~ laws), subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. For example, data breaches frequently result in regulatory actions and commercial and class action litigation based on a variety of laws and legal duties, such as the California Consumer Privacy Act (CCPA), which provides for a private right of action in the event of certain data security breaches. Additionally, the SEC ~~also~~ adopted a new cybersecurity rule requiring companies subject to SEC reporting requirements to formally report material cybersecurity incidents, where failure to report may result in regulatory investigations leading to consent orders that may require additional compliance obligations and / or injunctions, fines and other penalties. Such actions could result in significant legal and financial exposure and reputational damages that could have a material adverse effect on our business, financial condition, results of operations and prospects. Currently, we carry business interruption coverage and cybersecurity insurance to mitigate certain potential losses, but this insurance is limited in amount and may not be sufficient in type or amount to cover us against claims related to a cybersecurity breach and related business and system disruptions. We cannot be certain that such potential losses will not exceed our policy limits, insurance will continue to be available to us on economically reasonable terms, or at all, or any insurer will not deny coverage as to any future claim. In addition, we may be subject to changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements. We **obtain and process a large amount of proprietary and sensitive data. Any real or perceived improper use of, disclosure of, or access to such data could harm our reputation, as well as have an adverse effect on our business. We maintain and process, and our third- party vendors, collaborators, contractors and consultants maintain and process on our behalf, a large quantity of proprietary and sensitive information, including confidential business information, personal and patient health information in connection with our preclinical studies and clinical trials and personal information of our employees. There is a risk that we could be impacted by a cybersecurity incident that results in loss or unauthorized disclosure of this proprietary and sensitive information, potentially resulting in harm to our reputation and financial losses. Depending on the nature of the information compromised, in the event of a data breach or other unauthorized access to our customer data, we may also have obligations to notify customers and regulators about the incident, and we may need to provide some form of remedy, such as a subscription to credit monitoring services, pay significant fines to one or more regulators, or pay compensation in connection with a class-action settlement. Such breach notification laws continue to evolve and may be inconsistent from one jurisdiction to another. In the United States, the SEC has adopted rules for mandatory disclosure of cybersecurity incidents suffered by public companies, as well as cybersecurity governance and risk management. Complying with these obligations could cause us to incur substantial costs and could increase negative publicity surrounding any incident that compromises customer data. Any failure or perceived failure by us to comply with these laws may also subject us to enforcement action or litigation, any of which could harm our business. Additionally, the financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we may maintain, and there can be no assurance that the limitations of liability in any of our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. Any of the foregoing could have an adverse effect on our business, reputation, operating results, and financial condition. We** are ~~or may become~~ subject to a variety of stringent **and changing** privacy and data security laws, regulations, policies and contractual obligations related to data privacy and security, and changes in such laws, regulations, policies and contractual obligations and our failure, or any failure by our third- party vendors, collaborators, contractors or consultants, to comply with them could harm our business and result in enforcement action by regulators and claims from affected individuals. We ~~maintain~~ **are subject to global privacy** and ~~process,~~ **data protection laws** and **regulations that apply to the collection, transmission, storage and use of personal information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. Failure by us or** our third- party vendors, **CROs** ~~collaborators, contractors and consultants maintain and process on our behalf, a large quantity of proprietary and sensitive information, including confidential business information, personal and patient health information in connection with our preclinical studies and clinical trials and personal information of our employees. We are subject to global privacy and data protection laws and regulations that apply to the collection, transmission, storage and use of personal information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. Failure by us or our third- party vendors, collaborators~~ , contractors and consultants to comply with any of these laws and regulations could result in enforcement actions by data protection authorities against us, including fines or penalties, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these laws is subject to varying interpretations and the legislative landscape is constantly evolving. In particular, laws and regulations governing the privacy of health information, such as HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of

administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining how protected health information may be used, shared or processed in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. Further, if we fail to comply with applicable privacy laws, we could face civil and criminal penalties, or claims for breach of contract. The HHS has enforcement discretion for HIPAA, and any enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. **On April 22, 2024, OCR issued a Final Rule, HIPAA Privacy Rule to Support Reproductive Health Care Privacy, which is intended to strengthen the HIPPA Privacy Rule by prohibiting the disclosure of protected health information related to lawful reproductive healthcare in certain circumstances.** In addition, states have shown an increased interest in ~~protecting~~ **regulating personal information in general and specifically in** the privacy of health data. Washington state passed the My Health My Data Act, which **took** ~~will take~~ effect on March 31, 2024, and is focused on the collection of consumer health data. The My Health My Data Act has a broader scope than HIPAA and includes a private right of action — depending on whether this law applies to us, there may be substantial regulatory action and litigation associated with this act. Following Washington, Nevada enacted Senate Bill 370, which ~~will take~~ **also took** effect on March 31, 2024, and is similar to the My Health My Data Act and requires in- scope entities to comply with certain requirements regarding consumer health data. Notably, Senate Bill 370 does not include a private right of action nor does it apply to entities that are subject to HIPAA. Connecticut also amended its comprehensive privacy law in 2023, the Connecticut Data Privacy Act, to impose obligations aimed at " consumer health data. " Furthermore, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents pursuant to local state laws. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Personal ~~data~~ **information** privacy remains an evolving landscape at both the U. S. state and international level, with new regulations coming into effect. For example, the CCPA, which came into effect on January 1, 2020, and was amended and expanded by the California Privacy Rights Act (CPRA) as of January 1, 2023, provides California residents expanded privacy rights, including the right to request correction, access, and deletion of their personal information, the right to opt out of certain personal information sharing, and the right to receive detailed information about how their personal information is processed, including by California residents' employers. Additionally, the CCPA ~~, as amended,~~ requires companies that process personal information of California residents to make disclosures to consumers about their data collection, use and sharing practices, allow consumers to opt out of certain data sharing with third parties, complete certain audits and assessments when processing higher risk data and provide a private right of action for data breaches, as described above. Although the CCPA includes limited exceptions — including exceptions for personal health information collected by covered entities or business associates subject to HIPAA ~~among others~~, the CCPA may regulate or impact our processing of personal information depending on the context. Failure to comply with the CCPA may result in significant civil penalties, injunctive relief, or statutory or actual damages as determined by the California Privacy Protection Agency, the ~~newly created~~ state agency ~~from the CPRA legislation~~ that is charged with creating new rules and enforcing the CCPA, and the California Attorney General, who also still maintains some CCPA enforcement powers. Notably, following California' s lead, ~~several~~ **over a third of** other **U. S.** states enacted **or proposed** privacy laws that ~~took~~ **contain obligations similar to the CCPA and CPRA that have taken** effect **or will** ~~in 2023: the Colorado Privacy Act, the Connecticut Personal Data Privacy and Online Monitoring Act, the Utah Consumer Privacy Act, and the Virginia Consumer Data Protection Act. Additional state privacy laws are set to~~ take effect in **coming years. In addition** ~~2024: the Florida Digital Bill of Rights (July 1~~, **a comprehensive federal** ~~2024), Montana' s Consumer Data Privacy~~ **privacy bill** ~~Act (October 1~~, ~~2024), Oregon' s protections~~ **which includes a private right of action** for **violations, has been proposed and is under review by the U. S. House of Representatives. While** ~~the~~ **these** ~~personal~~ **new laws and proposals generally include exemptions for HIPAA- covered** data ~~of consumer enacted through SB 619 (July 1, 2024),~~ and **clinical trial data,** ~~the~~ **they** ~~Texas Data Privacy~~ **add layers of complexity to compliance in the U. S. market** and ~~Security Act (July 1, 2024)~~ **could increase our compliance costs and adversely affect our business** . Compliance with this new **and evolving** privacy legislation adds complexity and may require investment in additional resources for compliance programs, thus potentially result in additional costs and expense of resources to maintain compliance. In the EU, the EU GDPR governs the collection, use, disclosure, transfer, or other processing of personal data. The UK has implemented the EU GDPR as the UK GDPR which sits alongside the UK Data Protection Act 2018 (the UK GDPR ~~, and~~ together with the EU GDPR, the GDPR). The GDPR imposes compliance obligations on controllers **(and in more limited cases, on processors)** , including ~~(among others) mandating burdensome documentation requirements,~~ granting certain privacy rights to individuals to control how companies collect, use, disclose, retain and otherwise process ~~information about them~~ **their personal data** as well as specific requirements for obtaining valid consent where consent is the legal basis for processing, requirements around accountability and transparency, the obligation to consider data protection when any new products or services are developed, the obligation to appoint data protection officers in certain circumstances, the obligation to notify relevant data **protection** supervisory authorities of notifiable personal data breaches without undue delay (and no later than 72 hours) after becoming aware of the personal data breach, and the requirement ~~for~~ **to provide** more detailed notices for clinical trial subjects and investigators. In addition, the EU GDPR prohibits the international transfer of personal data **originating in the EEA (including,** from clinical trial sites and other third parties (e. g., CROs) **)** ~~located in the EEA~~ to jurisdictions that the European Commission does not recognize as having ' adequate' data protection laws, unless a data transfer mechanism has been put in place or a derogation under the EU GDPR can be relied upon. **In** ~~After years of uncertainty~~ ---- **certain cases** ~~following the July 16~~, **including when** ~~2020 decision of the Court of Justice of the European Union invalidating the EU- U. S. Privacy Shield~~

~~Framework for purposes of international~~ transfers ~~and imposing further restrictions~~ **are made in reliance** on ~~the use of~~ standard contractual clauses (EU SCCs), including a requirement for companies to carry out a transfer ~~privacy~~ impact assessment (TIA) ~~,~~ ~~on~~ **— which (among other things) assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under EU SCCs — will need to be implemented to ensure an ' essentially equivalent' level of data protection to that afforded in the EEA. On** July 10, 2023, the European Commission adopted its Final Implementing Decision granting the U. S. adequacy (Adequacy Decision) for EU- U. S. transfers of personal data for entities self- certified to the EU- U. S. Data Privacy Framework (DPF). Entities relying on EU SCCs for transfers to the United States are also able to rely on the analysis in the Adequacy Decision as support for their TIA regarding the equivalence of U. S. national security safeguards and redress. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to the monitoring of their behavior will be subject to the UK GDPR — the requirements of which at this time are largely aligned with those under the EU GDPR. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU Member States to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission reassesses and renews / extends that decision, and remains under review by the European Commission during this period. The UK GDPR also imposes similar restrictions on transfers of personal data from the UK to jurisdictions that the UK Government does not consider adequate, including the **United States** ~~U. S.~~. The UK' s Information Commissioner' s Office ~~(ICO)~~ published: (i) its own form of EU SCCs, known as the International Data Transfer Agreement ~~to replace the old Standard Contractual Clauses for transfers to outside the UK~~ ; (ii) a " UK addendum " to the ~~new~~ EU SCCs which amends the relevant provisions of such clauses to work in a UK context; and (iii) its own version of the TIA ~~and guidance on international transfers~~ (although entities may choose to adopt either the EU or UK- style TIA). Further, on September 21, 2023, the UK Secretary of State for Science, Innovation and Technology established a UK- U. S. data bridge (i. e., a UK equivalent of the Adequacy Decision) and adopted UK regulations to implement the UK- U. S. data bridge ~~(" UK Adequacy Regulations ")~~ . Personal data may now be transferred from the UK under the UK- U. S. data bridge through the UK extension to the DPF to organizations self- certified under the UK extension to the DPF **. However, the DPF in both the EU and UK may be subject to further legal challenge which could cause the legal requirements for personal data transfers from the EU and the UK to the United States to become uncertain once again. EU and UK data protection authorities have and may again block the use of certain U. S.- based services that involve the transfer of personal data to the United States. In the EU and other markets, potential new rules and restrictions on the flow of data across borders could increase the cost and complexity of doing business in those regions** . As a company, we have invested, and expect to continue to invest, significant time and resources in our GDPR compliance program. This is necessary to ensure we can initiate and maintain GDPR- compliant clinical trials in the EU or UK (as applicable). Any failure or perceived failure by us with respect to GDPR compliance could mean we either cannot initiate additional GDPR- compliant clinical trials in the EU or UK (as applicable) or we may face regulatory investigations, significant fines and penalties, reputational damage or be required to change our business practices, all of which could adversely affect our business, financial condition and results of operations. ~~There is a risk that we could be impacted by a cybersecurity incident that results in loss or unauthorized disclosure of personal data, potentially resulting in us facing harms similar to those described above.~~ Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity for conducting preclinical testing and clinical trials or delivering our future products, if any. Additionally, other countries (e. g., Australia and Japan) have adopted ~~certain~~ **their own** legal requirements for cross- border transfers of personal information. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, and our efforts to comply with the evolving data protection rules may be unsuccessful. In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time- intensive process, and we may be required to put in place additional mechanisms for ensuring compliance with the new data protection rules. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self- regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. It is possible that if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, or severe criminal or civil sanctions, all of which may have a material and adverse impact on our business, results of operations, reputation, and financial condition. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects. Any such liability, litigation, investigations and proceedings may or may not be covered by our liability insurance and may subject us to significant penalties and negative publicity, require us to change our business practices, increase our costs, severely disrupt our business, and may result in significant reputational harm and have a material and adverse impact on our business, financial condition, results of operations or prospects. **We use artificial intelligence in our business, and challenges with properly managing its use could result in reputational harm, competitive harm, and legal liability, and adversely affect our results of operations. We leverage artificial intelligence (AI) into certain aspects of our operations, including through our**

proprietary DEL- AI platform, which employs machine learning across all aspects of the discovery process. However, our competitors and other third parties may incorporate AI into their operations and processes more quickly or more successfully than us, which could impair our ability to compete effectively and adversely affect our results of operations. Additionally, if the output that AI applications assist in producing are or are alleged to be inaccurate, deficient, or biased, our business, financial condition, and results of operations may be adversely affected. Furthermore, the integration of third- party AI models with our operations relies on certain safeguards implemented by the third- party developers of the underlying AI models, including those related to the accuracy, bias, and other variables of the data, and these safeguards may be insufficient. The use of AI applications has resulted in, and may in the future result in, cybersecurity incidents that implicate the data analyzed within such applications. Any such cybersecurity incidents related to our use of AI applications to analyze data could adversely affect our reputation and results of operations. AI also presents emerging ethical issues and if our use of AI becomes controversial, we may experience brand or reputational harm, competitive harm, or legal liability. Legislation governing the development and use of AI has been passed or is under consideration in the United States at the state and local level, as well as internationally. As a result, the ability to use artificial intelligence and machine learning may be constrained by current or future laws, regulatory or self- regulatory requirements. The rapid evolution of AI, including regulation of AI and it various uses, will require significant resources to develop, test and maintain our platforms and AI operations to help us implement AI ethically in order to minimize unintended, harmful impact U. S. federal income tax reform and changes in other tax laws could adversely affect us **. U. S. federal, state, local and foreign tax laws, regulations and administrative guidance are subject to change as a result of the legislative process and review and interpretation by the U. S. Internal Revenue Service, the U. S. Treasury Department and other taxing authorities. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future** . In December 2017, U. S. federal tax legislation commonly referred to as the TCJA was signed into law, significantly reforming the Internal Revenue Code of 1986, as amended (Code). The TCJA, among other things, changed the U. S. federal tax treatment of research and experimental (R & E) expenses. For tax years beginning on or after January 1, 2022, taxpayers are required to capitalize and amortize, rather than deduct, R & E expenses. R & E expenses are amortizable over five years for research performed in the United States and 15 years for research performed outside the United States. Although there are legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Effective for transactions occurring on or after January 1, 2023, the IRA imposed a new one percent excise tax on certain repurchases of stock by publicly traded U. S. domestic corporations. The excise tax is imposed on the repurchasing corporation itself, not its shareholders from which shares are repurchased. For purposes of calculating the base excise tax, repurchasing corporations are permitted to net the fair market value of certain new stock issuances against the fair market value of stock repurchases during the same taxable year. Certain repurchases are not counted in the base of the excise tax. In addition, new legislation or regulations that could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax- related developments that could negatively impact our financial results. We use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax- related assumptions could have a material adverse effect on our business, results of operations, or financial condition. Our ability to utilize our net operating loss carryforwards may be subject to limitations. We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. As of November 30, ~~2023~~ **2024** , we had federal and state net operating loss (NOL) carryforwards of approximately $ ~~269~~ **263** . ~~3~~ **9** million and $ ~~410~~ **418** . ~~9~~ **7** million, respectively. To the extent we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, subject to the restrictions and exceptions described below. Federal NOLs generated in tax years beginning on or before December 31, 2017, may be carried forward 20 tax years and expire on various dates beginning in 2029. Under current law, NOLs arising in tax years beginning after December 31, 2017, may be carried forward indefinitely, but are limited to no more than 80 % of the excess, if any, of current year taxable income (without regard to certain deductions). Our state NOLs can be carried forward 20 years and begin expiring in 2029. Under Sections 382 and 383 of the Code, if a corporation undergoes an " ownership change " (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 NOLs and other pre- change tax attributes (such as ~~research tax~~ **R & D** ~~credits~~ **credit carryovers**) to offset its post- change income or post- change income tax may be limited. We have identified two ownership changes since our inception that have triggered a limitation on pre- change NOLs under ~~Section~~ **Sections** 382 **and 383** . A majority of our pre- change NOLs remain available within the carryforward period provided by the Code, subject to availability of taxable income. We may have experienced additional ownership changes that have not yet been identified that could result in the expiration of our NOL and credit carryforwards before utilization and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, if we earn net taxable income, our ability to use our pre- change NOLs and ~~tax~~ **R & D** credit carryovers to offset U. S. federal taxable income and tax liability may be subject to limitations that potentially could result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Future acquisitions, joint ventures, spin outs or strategic alliances or transactions could disrupt our business and harm our financial condition and results of operations. We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate

them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot be certain that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions include: • diversion of management time and focus from operating our business to addressing acquisition integration challenges; • coordination of research and development efforts; • retention of key employees from the acquired company; • changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition; • cultural challenges associated with integrating employees from the acquired company into our organization; • the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies; • liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities; • unanticipated write-offs or charges; and • litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties. Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions or cause us to incur unanticipated liabilities and harm the business generally. There also is a risk that future acquisitions will result in our incurring debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations. Additionally, we may not realize the expected value of out- licensing, joint ventures, spin outs or other strategic transactions. We are subject to anti- corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, or other remedial measures and legal expenses, any of which could adversely affect our business, results of operations and financial condition. Our operations are subject to anti- corruption laws, including the Foreign Corrupt Practices Act (FCPA), the Bribery Act and other anticorruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act and other anti- corruption or similar laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act or local anti- corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. We also are subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, UK and authorities in the EU, including **U. S. export controls, including the U. S. Department of Commerce' s Export Administration Regulations, and U. S. economic sanctions, trade sanctions regulations administered by the U. S. Department of the Treasury' s Office of Foreign Assets Controls, including restrictions or prohibitions on the sale or supply of certain products and services to U. S.- embargoed or sanctioned countries, governments, persons and entities, and other** applicable export control regulations ~~, economic sanctions on countries and persons~~ , customs requirements and currency exchange regulations, which we collectively refer to as Trade Control Laws. There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act, or other legal requirements including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act, and other anti- corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, legal expenses, and disgorgement and other sanctions and remedial measures, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission (SEC) also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Likewise, any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control Laws by U. S., UK or other authorities also could have an adverse impact on our reputation, our business, results of operations and financial condition. 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 significantly 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. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may produce hazardous waste products. Although we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our 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. We maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but 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 addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis of 2007- 2008 caused extreme volatility

and disruptions in the capital and credit markets. Similarly, the volatility associated with the COVID- 19 pandemic caused significant instability and disruptions in the capital and credit markets and, more recently, the global economy has been impacted by ~~increasing~~ interest ~~rates~~ **rate fluctuations** and inflation, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, as well as the possibility of a recession or further economic downturn. Moreover, there have been **concerns in** recent ~~concerns~~ **years** with respect to the stability of the global banking system. For example, ~~on~~ **in** March ~~10,~~ 2023, Silicon Valley Bank (SVB), which was one of our banking partners, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver ~~. Similarly~~ , ~~on~~ **and in** March ~~12,~~ 2023, Silvergate Capital Corp. and Signature Bank were ~~each~~ **similarly** swept into receivership. While we only had a minimal amount of our cash directly at SVB and the FDIC took steps to make depositors of SVB whole such that we regained access to this cash, there is no assurance that similar guarantees will be made in the event of further bank closures and continued instability in the global banking system. Our ongoing cash management strategy is to maintain diversity in our deposit accounts across financial institutions, but deposits in these institutions may exceed the amount of insurance provided on such deposits and there can be no assurance that this strategy will be successful. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, then our ability to access our cash, cash equivalents and marketable securities may be threatened, which could have a material adverse effect on our business and financial condition. Furthermore, the capital and credit markets may be adversely affected by regional conflicts around the world and the possibility of a wider global conflict, global sanctions imposed in response to regional conflicts or an energy crisis. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including weakened demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn. Our current operations are in the San Francisco Bay Area, and we or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters as to which our business continuity and disaster recovery plans may not be adequate to protect us. Our current operations are located in our facilities in San Francisco, California. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or man- made accident or incident that results in our being unable to fully utilize our facilities, or the manufacturing facilities of our third- party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our drug candidates or interruption of our business operations, and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure such as our research facilities or the manufacturing facilities of our third- party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third- party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects. Risks Related to Our Common Stock Our quarterly results of operations may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. We expect our results of operations to be subject to quarterly fluctuations. Our net loss and other results of operations will be affected by numerous factors, including: • variations in the level of expense related to the ongoing development of our drug candidates, ~~DELigase~~ **DEL- AI** platform, or future development programs; • results of preclinical studies and clinical trials, or the addition or termination of clinical trials or funding support by us or by existing or future collaborators or licensing partners; • our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements; • any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved; • additions and departures of key personnel; • strategic decisions by us or our competitors, such as acquisitions, divestitures, spin- offs, joint ventures, strategic investments or changes in business strategy; • if any of our drug candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such drug candidates; • regulatory developments affecting our drug candidates or those of our competitors; and • changes in general market and economic conditions, including ~~increasing~~ interest ~~rates~~ **rate fluctuations** , inflation, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, instability in the global banking system and the possibility of a recession or further economic downturn. If our quarterly results of operations fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our results of operations may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Our stock price may be volatile and you

could lose all or part of your investment. The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the purchase price. The market price for our common stock may be influenced by many factors, including the other risks described in this " Risk Factors " section and the following: • results of preclinical studies and clinical trials of our drug candidates, or those of our competitors or our existing or future collaborators; • regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our drug candidates; • the success of competitive products or technologies; • introductions and announcements of new products by us, our collaboration partners, or our competitors, and the timing of these introductions or announcements; • actions taken by regulatory agencies with respect to our drug candidates, clinical trials, manufacturing process or sales and marketing terms; • actual or anticipated variations in our financial results or in those of companies that are perceived to be similar to us; • the success of our efforts to acquire or in- license additional technologies, products or drug candidates; • developments concerning our current or future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners; • market conditions in the pharmaceutical and biotechnology sectors; • announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments; • developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drug candidates and products; • our ability or inability to raise additional capital and the terms on which any additional capital is raised; • the recruitment or departure of key personnel; • changes in the structure of healthcare payment systems; • actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally; • our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may provide to the market; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • announcement and expectation of additional financing efforts; • speculation in the press or investment community; • trading volume of our common stock; • sales of our common stock by us or our stockholders; • the concentrated ownership of our common stock; • changes in accounting principles; • cybersecurity events; • terrorist acts, acts of war or periods of widespread civil unrest, including the increasingly volatile global economic conditions resulting from regional conflicts around the world; • effects of public health crises, pandemics and epidemics; • natural disasters and other calamities; and • general economic, industry and market conditions, including ~~increasing~~ interest ~~rates~~ **rate fluctuations** , inflation, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, instability in the global banking system and the possibility of a recession or further economic downturn. In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that often have been unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and adverse impact on the market price of our common stock. A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or vesting and settlement of outstanding restricted stock units, or the perception that such sales may occur, could adversely affect the market price of our common stock. We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our common stock is and will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the analysts or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume. The future sale and issuance of equity or of debt securities that are convertible into equity will dilute our share capital. We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. For example, in March 2021, we sold an additional 5, 175, 000 shares of our common stock in a follow- on public offering **; in July 2022, we entered into separate Securities Purchase Agreements with certain purchasers to issue and sell pre- funded warrants to purchase an aggregate of 6, 814, 920 shares of our common stock in registered direct offerings; and in April 2024, we sold an additional 11, 916, 667 shares of our common stock and pre- funded warrants to purchase an aggregate of 1, 500, 100 shares of our common stock in a public offering. Such pre- funded warrants are immediately exercisable, have an exercise price of $ 0. 001 and may be exercised at any time after the date of issuance** . In addition, we currently have on file with the SEC ~~a~~ **an automatic** shelf registration statement on Form S- 3 which allows us to offer and sell ~~up to $ 450. 0 million of~~ our registered common stock, preferred stock, debt securities, warrants, subscriptions rights and or units from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. In August 2021, we

entered into an Equity Distribution Agreement with Piper Sandler & Co. (Piper Sandler) **, which was amended in July 2024 and again in October 2024 (as amended, the Second Amended Equity Distribution Agreement),** pursuant to which, from time to time, we may offer and sell through Piper Sandler up to $ ~~150~~ **300** . 0 million of the common stock registered under the shelf registration statement pursuant to one or more " at the market " offerings. ~~In June 2022~~ **From time to time** , we **have** issued and sold ~~2, 000, 000~~ shares of common stock **pursuant to this** ~~under the Equity Distribution Agreement~~ **agreement and as** ~~to Piper Sandler for net proceeds~~ of ~~approximately~~ **the date of this filing, we have** $ ~~19~~ **204** . **6** ~~3 million, after deducting offering commissions and expenses paid by us. As of November 30, 2023, we had $ 130. 0~~ million of common stock remaining available for sale **under** ~~pursuant to~~ the **Second Amended** Equity Distribution Agreement. Sales of our common stock under the **Second Amended** Equity Distribution Agreement with Piper Sandler could be subject to business, economic or competitive uncertainties and contingencies, many of which may be beyond our control, and which could cause actual results from the sale of our common stock to differ materially from expectations ~~. In addition, in July 2022, we entered into separate Securities Purchase Agreements with certain purchasers to issue and sell pre- funded warrants to purchase an aggregate of 6, 814, 920 shares of our common stock in registered direct offerings for gross proceeds to us of $ 95. 0 million before deducting offering expenses. Such pre- funded warrants are immediately exercisable, have an exercise price of $ 0. 001 and may be exercised at any time after the date of issuance~~ . To the extent additional capital is raised through the sale and issuance of shares or other securities convertible into shares, the ownership interest of our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock. We will not receive a significant amount, or potentially any, additional funds upon the exercise of our pre- funded warrants; however, any exercise would increase the number of shares eligible for future resale in the public market and result in substantial dilution to our stockholders. As of November 30, ~~2023~~ **2024** , we have issued pre- funded warrants to purchase a total of ~~6~~ **8** , ~~814~~ **315** , ~~920~~ **020** shares of our common stock, of which ~~6~~ **7** , ~~097~~ **577** , ~~560~~ **909** were outstanding as of November 30, ~~2023~~ **2024** . Each pre- funded warrant is exercisable for $ 0. 001 per share of common stock underlying such pre- funded warrant, which may be paid by way of a cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre- funded warrant. Accordingly, we will not receive a significant amount, or potentially any, additional funds upon the exercise of the pre- funded warrants. To the extent such pre- funded warrants are exercised, additional shares of common stock will be issued for nominal or no additional consideration, which will result in substantial dilution to the then existing holders of our common stock and will increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of the common stock, causing our stock price to decline. There is no public market for our pre- funded warrants. There is no public trading market for our pre- funded warrants issued, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre- funded warrants on any securities exchange or nationally recognized trading system, including the Nasdaq Global Market (Nasdaq). Without an active market, the liquidity of the pre- funded warrants will be limited, and the value of the pre- funded warrants may be adversely impacted. Additionally, each holder of pre- funded warrants will not be entitled to exercise any portion of any pre- funded warrant, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 9. 99 % of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 9. 99 % of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise. However, any holder may increase or decrease such percentage to any other percentage (not in excess of 19. 99 %) upon at least 61 days' prior notice from the holder to us. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Our restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions also could make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or to take other corporate actions, including effecting changes in our management. These provisions: • establish a classified board of directors so that not all members of our board are elected at one time; • permit only our board of directors to establish the number of directors and fill vacancies on our board; • provide that directors may be removed only " for cause " and only with the approval of two- thirds of our stockholders; • require super- majority voting to amend some provisions in our restated certificate of incorporation and amended and restated bylaws, unless such amendments are approved by two- thirds of our board of directors, in which case stockholders can approve by a simple majority; • authorize the issuance of " blank check " preferred stock that our board could use to implement a stockholder rights plan; • eliminate the ability of our stockholders to call special meetings of stockholders; • prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders; • prohibit cumulative voting; and • establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings. In addition, Section 203 of the Delaware General Corporation Law (DGCL) may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15 % or more of our common stock. Our restated certificate of incorporation and our amended and restated bylaws contain exclusive forum provisions for certain claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought

on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Moreover, Section 22 of the Securities Act of 1933, as amended (the Securities Act) creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and our amended and restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (a Federal Forum Provision). Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder and neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit our stockholders' ability to bring a claim in a judicial forum they find favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our restated certificate of incorporation and / or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations which impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Compliance with these rules and regulations may strain our financial and management systems, internal controls, and employees. For example, the Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and results of operations and the disclosure requirements under the Exchange Act are subject to change from time to time. ~~For example, in 2023 the SEC adopted rules requiring disclosure of material cybersecurity incidents suffered by public companies, as well as annual disclosure regarding cybersecurity governance and risk management.~~ Complying with these new disclosure obligations once applicable to our company, or any or any additional new disclosure requirements that may apply to us in the future, could cause us to incur substantial costs and could increase negative publicity surrounding any incident that we are required to disclose. Any failure or perceived failure by us to comply with these obligations may also subject us to enforcement action or litigation, any of which could harm our business. Therefore, as a result of being a public company, our management and other personnel are required to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time- consuming and costly. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements also could make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Moreover, these rules and regulations often are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. If we fail to maintain effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could harm our results of operations, investors' views of us and, as a result, the value of our common stock. Pursuant to the rules and regulations of the SEC, we are required to furnish a report by our management on, among other things, our internal control over financial reporting. To achieve compliance with these rules and regulations, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and time- consuming. Effective internal control over financial reporting is necessary for us to provide reliable financial reporting and, together with adequate disclosure controls and procedures, are designed to prevent material misstatements due to fraud or error. Any failure to design new or improved internal controls necessary to address risks of material misstatement in our interim or annual financial statements, or difficulties encountered in their implementation or operation, could cause us to fail to meet our reporting obligations. Ineffective internal control over financial reporting could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. The reporting on our assessment of the effectiveness of our internal control over financial reporting needs to include disclosure of any material weaknesses identified in our internal control over financial reporting. Moreover, ~~in~~ **based on** the ~~event that we qualify~~ **market value of our common stock held by non- affiliates** as **of May 31, 2024, we are considered** a large ~~accelerated filer or~~ accelerated filer under SEC rules ~~in future years~~ **effective November 30, 2024, and, as a result** , our independent registered public accounting firm **is** ~~will be~~ required to audit the effectiveness of our internal control over financial reporting pursuant to Section 404 (b) of the Sarbanes-

Oxley Act (Section 404 (b)). ~~Any mandatory or voluntary compliance~~ **Compliance** with Section 404 (b) will result in increased costs, expenses, and management resources. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. For example, we previously identified material weaknesses in our internal control over financial reporting for the fiscal year ended November 30, 2021, related to controls over segregation of duties in our journal entry and account reconciliation processes, and certain information technology general controls. The material weaknesses identified did not result in any misstatement of our financial statements and during the year ended November 30, 2022, the material weaknesses was remediated. However, we cannot assure you that the measures we have taken to date, and actions we may take in the future, will prevent or avoid potential future material weaknesses. We are also required to disclose changes made in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, internal control over financial reporting on a quarterly basis. To comply with the requirements of being a public company, we have undertaken, and may need to further undertake in the future, various actions, such as implementing new internal controls and procedures and hiring additional accounting staff. Moreover, our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, material weaknesses in our disclosure controls and procedures and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective internal control over financial reporting or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods, which could cause the price of our common stock to decline. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq. We ~~are~~ **no longer qualify as** a " smaller reporting company " and **, commencing with our quarterly report on Form 10- Q for** the **fiscal quarter ending February 28, 2025, we may no longer take advantage of** reduced disclosure **and reporting** requirements applicable to smaller reporting companies ~~may~~ **. Based on the** ~~make~~ **market value of** our common stock ~~less attractive to investors. We became~~ **held by our non- affiliates as of May 31, 2024, we no longer qualify as** a " smaller reporting company " as ~~of May 31~~ **defined by the SEC effective November 30** , ~~2022~~ **2024** . ~~We~~ **Therefore, beginning with our quarterly report on Form 10- Q for the fiscal quarter ending February 28, 2025, we** will ~~continue to~~ **no longer** be ~~a~~ **eligible to rely on the reduced disclosure and reporting requirements applicable to** smaller reporting ~~company~~ **companies** ~~so long as either (i) the market value of our stock held by non- affiliates is less than $ 250~~ . ~~0 million as~~ **Moreover, we have chosen not to take advantage** of the **reduced disclosure** ~~prior May 31 or (ii) our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year~~ and **reporting requirements applicable to** ~~the market value of our stock held by non- affiliates is less than $ 700. 0 million as of the prior May 31. As a~~ smaller reporting **companies starting with this Annual Report on Form 10- K. Any failure to** ~~company~~ **comply with** ~~, we may take advantage of many of~~ the **increased** ~~same exemptions from~~ disclosure **and reporting** requirements ~~as~~ **could have** an **adverse effect** ~~emerging growth company, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely~~ on ~~these exemptions. If some investors find~~ our **business, financial condition and** ~~common stock less attractive as a result~~ **results of operations** ~~, there may be a less active trading market for our common stock and our stock price may be more volatile~~ . Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. We may be subject to securities litigation, which is expensive and could divert management attention. The market price of our common stock may be volatile. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business.