Risk Factors Comparison 2024-03-18 to 2023-03-20 Form: 10-K

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

Investing ~~An investment~~ in **shares of** our common stock involves ~~various~~ **a high degree of** ~~risks~~ **risk** ~~, and prospective investors are urged to carefully consider the matters discussed in the section titled " Risk Factors " prior to making an investment in our common stock. These risks include, but are not limited to, the following: • We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future may not be successful. If we are able to complete any such transaction, it may not result in additional value to stockholders and may present additional challenges. We may also elect to pursue a dissolution and liquidation of the Company instead of a strategic transaction, which may impact the timing and amount of payments to our stockholders. • We will require substantial additional capital to finance our operations which may not be available to us on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of our product candidates. • The price of our common stock does not meet the requirements for continued listing on Nasdaq. If we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted. • We have incurred significant losses in every quarter since our inception and anticipate that we will continue to incur significant losses in the future. • We have a limited operating history as a company developing therapies using de novo protein design technology, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability. • We currently have no source of product revenue and may never become profitable. • Our product candidates are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of, or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed. • Our business is heavily dependent on the success of our Neoleukin design process. Preclinical studies and clinical trials of our product candidates may not be successful, and if we are unable to commercialize these product candidates or experience significant delays in doing so, our business will be materially harmed. • Future clinical trials or additional preclinical studies may reveal significant adverse events not seen in our earlier preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates. • If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline. • Our approach to the discovery and development of our therapeutic treatments is based on de novo protein design technology which is unproven and may not result in marketable products. • We rely on and expect to continue to rely on third parties to conduct certain of our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines, or terminate the relationship, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations, and prospects. • We rely on and expect to continue to rely on third- party manufacturers and suppliers to supply components of our product candidates. The loss of our third- party manufacturers or suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business. • Unfavorable global economic conditions or other geopolitical developments could adversely affect our business, financial condition, stock price, and results of operations. • If we are not able to obtain, maintain, and enforce patent protection and other intellectual property rights for our product candidates, our Neoleukin design process technology, or other proprietary technologies we may develop, the development and commercialization of our product candidates may be adversely affected~~ . You should carefully consider the following ~~risk~~ **risks** ~~factors~~ **and uncertainties** ~~, in addition to~~ **together with all of** the other information contained in this Annual Report on Form 10- K **before making** ~~and~~ **an investment decision** ~~the information incorporated by reference herein~~ . ~~If~~ **The occurrence of** any of the ~~events described in the~~ following ~~risk~~ **risks** ~~factors occurs,~~ **could materially and adversely affect** our business, ~~operating results and~~ financial condition **, reputation, or** ~~could be adversely affected. This Annual Report on Form 10- K also contains forward- looking statements that involve risks and uncertainties. Our actual~~ results ~~could differ materially from those anticipated in the forward- looking statements as a result~~ of ~~factors that are described below and elsewhere in this Annual Report on Form 10- K. Risks Related to Strategic Process and Potential Strategic Transaction In November 2022, we made the strategic decision to wind down our clinical trial of NL- 201, a de novo protein designed to mimic the therapeutic activity of the cytokines interleukin- 2, or IL- 2, and interleukin- 15, or IL- 15, for the potential treatment of various types of cancer. In connection with that decision, our Board of Directors, or Board, approved a reduction in our workforce designed to reduce our operating expenses to increase our cash runway. In March 2023, based on the challenging capital markets and resources required to bring our earlier stage programs forward to a point of potential viability, the Board approved a plan to significantly reduce the remainder of our workforce while we undertake a comprehensive assessment of strategic options to maximize stockholder value. These strategic options may include a merger, reverse merger, sale, wind- down, liquidation and dissolution or other strategic transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time- consuming and complex and we may incur significant costs related to this continued evaluation. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our**

stockholders. In addition, we may not be able to adequately limit or avoid future liabilities, including future costs relating to the lease on our headquarters, which may impair the value of any potential transaction or present additional challenges to completing a strategic transaction. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly reduce or delay any future distributions to our stockholders. We may not realize any additional value in a strategic transaction. The market capitalization of our company is below the value of our current cash, cash equivalents and investments. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets, including NL- 201 and our de novo protein design methodology. Further, the development and any potential commercialization of our product candidates would require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend the additional resources necessary to continue developing our product candidates and may attribute little or no value, in such a transaction, to those product candidates. If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks. Although there can be no assurance that a strategic transaction will result from the process we have undertaken to assess strategic options, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management' s attention may disrupt our the orderly operation of our company. The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including: • increased near- term and long- term expenditures; • exposure to unknown liabilities • higher than expected acquisition, disposition or integration costs; • incurrence of substantial debt or dilutive issuances of equity securities to fund future operations • write- downs of assets or incurrence of non- recurring, impairment or other charges; • difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel • impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership • inability to retain key employees of our company or any acquired business; and • possibility of future litigation Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects Our decision to wind down our clinical trial of NL- 201, suspend our early stage research and development work and significantly reduce our workforce may not result in the anticipated savings and could disrupt our business. In November 2022, we made the decision to wind down our clinical trial of NL- 201 and restructure our research team to focus early stage, next generation de novo protein design for immunotherapies. In March 2023, we decided to further restructure the Company by suspending our early stage research and development and further reducing our workforce with the goal of substantially reducing our operating expenses while we undertake a comprehensive assessment of strategic options to maximize stockholder value. We may not realize, in full or in part, the anticipated benefits and savings in operating expenses from these decisions due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected cost savings, our financial condition would be adversely affected and it may be more difficult to complete a potential strategic transaction. Furthermore, the reduction in our workforce may result in weaknesses in our infrastructure and operations and may increase the risk that we become unable to comply with legal and regulatory requirements. Our Board may decide to pursue a dissolution and liquidation . In such an event, the amount of cash **case** available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities. There can be no assurance that a strategic transaction will be completed and , whether or not such strategic transaction is completed, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other -- **the trading price of shares** claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could **decline, and you may** lose all or a **part of your investment. It is not possible to predict or identify all such risks; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present** significant **risks to** portion of their investment in the event of a liquidation, dissolution or **our operations** winding up . Our ability **Therefore, you should not consider the following risks** to consummate **be** a strategic transaction depends on **complete statement of all the potential risks** our - **or uncertainties that** ability to retain our employees required to consummate such transaction. Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, and the loss of such employees' services may adversely impact the ability to consummate such transaction. In March 2023, we implemented **face. Summary of Risk Factors • We have** a **limited** further reduction in our workforce designed to substantially reduce our operating **history** expenses while we undertake a comprehensive assessment of strategic options to maximize stockholder value. Our cash conservation activities may yield unintended consequences , **have** such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of strategic options as well as business

~~operations. We may become involved in securities class action litigation that could divert management' s attention and harm the company' s business, and insurance coverage may~~ not **completed** ~~be sufficient to cover all costs and damages. In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of~~ any ~~other strategic transaction, or the announcement of negative events, such as negative results from~~ clinical trials **, and have** ~~. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if~~ no **products approved** ~~wrongdoing occurred. Litigation and investigations are usually expensive and divert management' s attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or~~ **for commercial sale,** ~~the ultimate value our stockholders receive in any such transaction. Risks Related to Our Financial Position~~ and ~~Capital Needs~~ **our results may vary from quarter to quarter. •** We will require substantial additional capital to ~~complete a strategic transaction and~~ finance **our operations in the** future **. If we are unable** ~~operations, which may not be available~~ to ~~us~~ **raise such capital when needed, or** on acceptable terms, **we may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts. • We have incurred significant losses since inception, and expect to incur significant losses** ~~or~~ **for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable. • NGN- 401, NGN- 101 and our other programs are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. • We are substantially dependent on the success of our most advanced product candidates, NGN- 401 and NGN- 101, and our ongoing and anticipated clinical trials of such candidates may not be successful. • Delays in developing our manufacturing capabilities or failure to achieve operating efficiencies from such capabilities may require us to devote additional resources and management time to manufacturing operations and may delay our product development timelines. • We have a number of academic collaborations, and currently rely on our collaboration with the University of Edinburgh for certain aspects of our preclinical research and development programs, including working in collaboration to discover and preclinically develop our lead product candidate for Rett syndrome and our near- term future pipeline. Failure or delay of the University of Edinburgh or any other collaborator to fulfil all or part of its obligations under our agreement, a breakdown in collaboration between the parties or a complete or partial loss of the relationship would materially harm our business. • In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth. • The regulatory approval processes of the U. S. Food and Drug Administration (" FDA ") and other comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, such product candidates, and our ability to generate revenue will be materially impaired. • The market price of our common stock may continue to be volatile. • If our legacy lease obligations are not subleased, assigned, terminated or otherwise addressed or the legacy assets subject to the CVR Agreement are not sold, respectively, in a timely manner, we may have to incur time and resources to take such actions. • Future sales of shares by existing stockholders could cause our stock price to decline. • Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval. Risks Related to Neurogene' s Limited Operating History, Financial Position and Capital Requirements We are a clinical- stage biotechnology company with limited operating history. Since our inception in 2018, we have incurred significant operating losses and have used substantially all of our resources to conduct research and development activities, preclinical studies and Phase 1 / 2 clinical trials of our most advanced product candidates, establish in- house manufacturing capabilities, including analytical and process development operations to support ongoing manufacturing operations, manufacture product candidates, conduct business planning, develop and maintain our intellectual property portfolio, hire personnel, raise capital, and provide general and administrative support for these activities. We have little experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, we cannot be certain that our current and planned clinical trials will begin or be completed on time, if** at all. ~~If~~ **In addition, while** we ~~fail~~ **are conducting a Phase 1 / 2 clinical trial of NGN- 401 in patients with Rett syndrome and a Phase 1 / 2 clinical trial of NGN- 101 in patients with CLN5 Batten disease, we have not yet demonstrated our ability** to **successfully complete clinical trials (including Phase 3 or other pivotal clinical trials),** obtain **regulatory or marketing approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities** necessary **for successful product commercialization. Additionally, we expect our** ~~financing~~ **financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors** , ~~we may~~ **many of which are beyond our control. Consequently, any predictions made about our future success or viability may not** be ~~unable~~ **as accurate as they could be if we had a longer operating history. In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with an early research and development focus to a company capable of supporting larger pivotal clinical trials and eventually commercial activities, including the manufacture of commercial scale product. We may not be successful in such a transition. Developing biotechnology products is a long, time- consuming, expensive and uncertain process that takes years** to complete ~~the development and potential commercialization of any future product candidates~~ . ~~The development~~ **Since our inception, we have funded our operations primarily through private financings and have incurred significant recurring losses, including net losses** of **$ 36** ~~biopharmaceutical product candidates is capital- intensive~~ . ~~As of~~ **3 million and $ 55. 2 million for the years ended** December 31, **2023 and** 2022, **respectively** ~~we had approximately $ 96~~ . ~~4 million~~ **We expect our expenses to increase** in **connection with our ongoing activities, particularly as we continue to conduct a Phase**

1 / 2 clinical trial of NGN- 401 in patients with Rett syndrome and a Phase 1 / 2 clinical trial of NGN- 101 in patients with CLN5 Batten disease, with the expectation that we will also initiate additional clinical trials in the future, and continue to research, develop and conduct preclinical studies of our other potential product candidates. In addition, if we obtain regulatory approval for any product candidate for commercial sale, including NGN- 401 and NGN- 101, we anticipate incurring significant commercialization expenses related to product manufacturing, marketing, sales and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our current, planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Our future capital requirements depend on many factors, including factors that are not within our control. We incur additional costs associated with operating as a public company, and we do not anticipate achieving any significant revenue in the near term given the development stage of our product candidates. Accordingly, we will require substantial additional funding to continue our operations. Based on our current operating plan, we believe that our existing cash, cash equivalents ~~,~~ and short- term investments **should be sufficient to fund its** ~~. We have spent a significant amount of money on our~~ operations **into** ~~to date, including research and development, preclinical and clinical studies. We will continue to incur costs related to~~ the ~~discontinued development~~ **second half** of **2026** ~~NL- 201 and suspension of our research and development activities~~ . ~~Based on our current operating plan, we believe that our available cash, cash equivalents, and short- term investments will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months following the filing date of this~~ **This estimate is** ~~Form 10- K. However, our current operating plan does not contemplate the resumption of research and development activities or the commencement of any clinical trials, and we do not expect to be able to fully support our operations~~ based on ~~the~~ assumptions ~~of~~ that ~~operating plan. We announced in March 2023 that we have suspended our research and development operations so that we can focus on reviewing strategic alternatives, which~~ may ~~include a sale~~ **prove to be materially wrong** , **and we could deplete** ~~merger, divestiture of assets, licensing or~~ **our available capital resources sooner than** ~~other strategic alternative, with the intention of improving shareholder value, While~~ we **currently** expect **. Our** ~~to have adequate capital to fund our operations through this process, our~~ future capital requirements ~~and the period during which we expect to complete this strategic process may vary significantly from what we expect, and we may have to seek an alternate resolution to the process. In addition, even if we are successful in completing a strategic transaction, we may still need to raise additional funds for any research and development or clinical programs we may pursue in the future. Our monthly spending levels may vary, and may also be impacted by inflationary pressures in the current economic environment. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, and because we have suspended our research and development activities while we pursue strategic alternatives, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for any product candidates that ultimately may be approved for sale. Our future funding requirements, both near and long- term,~~ will depend on many factors, including ~~, but not limited to~~ : ~~• our ability to complete a strategic transaction in a timely manner and on acceptable terms; •~~ the timing ~~, cost~~ and progress of ~~research,~~ preclinical ~~,~~ and clinical development activities; • the number and scope of ~~development,~~ preclinical and clinical programs we ~~decide to~~ pursue **to develop our gene therapy candidate pipeline and EXACT platform** ; • ~~the terms of any collaborations and / or~~ **our ability to secure appropriate animal models** ~~research and development agreements we may enter into, which may impact the cost, timing and development plans of one or~~ **for** ~~more~~ **the conduct** of ~~our product candidate programs~~ **investigational new drug (" IND ")- enabling studies in a timely and financially feasible manner, especially large animal models, such as non- human primates (" NHPs ") needed for toxicology studies** ; • our ability to ~~maintain our current licenses and to~~ establish ~~new collaboration arrangements~~ **an acceptable safety profile with IND- enabling toxicology studies to enable clinical trials** ; • **successful patient enrollment in, and** the **initiation and completion of, larger and later- stage clinical trials; • the number of subjects that participate in clinical trials and per subject trial** costs ~~involved~~ **; • the number and extent of trials required for regulatory approval; • the countries** in ~~prosecuting~~ **which the trials are conducted; • the length of time required to enroll eligible subjects in clinical trials; • the drop- out and discontinuation rate of subjects; • potential additional safety monitoring requested by regulatory agencies; • the duration of subject participation in the trials and follow- up; • the extent to which we encounter any serious adverse events in our clinical trials; • the timing of receipt of regulatory approvals from applicable regulatory authorities, including those required to initiate clinical trials; • the timing, receipt and terms of any marketing approvals and post- marketing approval commitments from applicable regulatory authorities; • the extent to which we establish collaborations, strategic partnerships, or other strategic arrangements with third parties, if any, and the performance of any such third party; • the scale up of our clinical and regulatory capabilities, including establishing our current good manufacturing practices (" cGMP ") manufacturing capabilities to support expansion of our pipeline and future registration- enabling clinical trials, and obtaining cGMP material for clinical trials or potential commercial sales; • hiring and retaining research, clinical, regulatory, manufacturing (including quality control and quality assurance) and administrative personnel; • our arrangements with third- party contract development and manufacturing organizations (" CDMOs ") and contract research organizations (" CROs "); • the build- out and validation of our cGMP manufacturing facility, including expansion to commercial scale; • the impact of any business interruptions to our operations or to those of the third parties with whom we work; and • obtaining, maintaining, defending** and enforcing patent **claims** and other intellectual property **rights. We do not have** ~~claims; • the costs of manufacturing our product candidates by third parties; • the cost of regulatory requirements, regulatory submissions and timing of regulatory approvals; • the potential delays in our preclinical studies, our development programs and our ongoing and planned clinical trial activities due to the effects of global events,~~

~~including macroeconomic conditions and continued supply chain disruptions; • the impact of inflationary pressures on salaries and wages, and costs of goods and transportation expenses, among other things; • the cost of commercialization activities if~~ any **committed external sources** ~~future product candidates are approved for sale, including marketing, sales and distribution costs; and • our efforts to enhance operational systems and hire personnel to support development~~ of ~~any future product candidates. If we are unable~~ **funds and adequate additional financing may not be available** to **us** ~~obtain funding on a timely basis or~~ on acceptable terms, ~~we may have to pursue less advantageous strategic opportunities, limit future research and development, or dissolve the Company and liquidate our~~ **or** ~~assets. We do not expect to realize revenue from sales of commercial products or royalties from licensed products in the foreseeable future, if~~ at all ~~, and, in no event would we recognize such revenues before any future product candidates are clinically tested, approved for commercialization, and successfully marketed~~ . We may **be required to** seek ~~the~~ additional **funds sooner than planned** ~~funding we will need to continue operating in the future~~ through ~~collaborations and / or licensing agreements,~~ public or private equity offerings ~~or~~ **,** debt financings, ~~credit~~ **collaborations and licensing arrangements** or **other** ~~loan facilities, or a combination of one or more of these funding~~ sources. ~~If we raise~~ **Such financing may dilute our stockholders or the failure to obtain such financing may restrict our operating activities. Any** additional **fundraising efforts may divert** ~~funds by issuing equity securities,~~ our **management from** ~~stockholders will suffer dilution and the~~ **their** ~~terms of any financing~~ **day- to- day activities, which** may adversely affect **our business. To the extent that Neurogene raises additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or** ~~the~~ **other preferences and anti- dilution protections that adversely affect your** rights ~~of our stockholders. In addition,~~ as a ~~condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders~~ **stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business** . If we ~~are able to~~ raise additional funds through **upfront payments or milestone payments pursuant to** future ~~debt financings, the terms of such financings are likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. If we raise additional funds through licensing or collaboration~~ **collaborations** ~~arrangements~~ with third parties, we may have to relinquish valuable rights to ~~our~~ product ~~candidates~~ **development programs,** or grant licenses on terms that are not favorable to us. **Our ability** ~~We also could be required~~ to **raise additional** ~~seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish some or all of our rights to certain product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Failure to obtain~~ capital **may be adversely impacted by global macroeconomic conditions and volatility in the credit and financial markets in the United States and worldwide, over which we may have no or little control. Our failure to raise capital as and** when needed **or** on acceptable terms ~~may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could~~ **would** have a **negative impact** ~~material and adverse effect~~ on our ~~business,~~ financial condition ~~, results of operations,~~ and ~~prospects~~ **our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate clinical trials, product development programs or future commercialization efforts** . We ~~are a~~ **have incurred significant losses since inception, expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable. Investment in** biotechnology **product** ~~company with a limited operating history of developing~~ **development** ~~next- generation immunotherapies for cancer, inflammation, and autoimmunity using de novo protein design technology. Investment in biotechnology~~ is **a** highly speculative ~~because it~~ **undertaking and** entails substantial upfront ~~capital~~ expenditures and significant ~~risk~~ **risks** that any **program** ~~potential product candidate~~ will fail to demonstrate adequate ~~effect~~ **efficacy or potency** or an acceptable safety profile, gain regulatory approval **and** ~~, or~~ become commercially viable. We ~~do not~~ have ~~any~~ **no** products approved ~~by regulatory authorities~~ for ~~marketing or~~ commercial sale, **has** ~~we have~~ not generated any revenue from product sales to date, ~~all of~~ **and continues to incur significant research and development and other expenses related to our ongoing operations. We do not expect to generate product revenue unless** ~~our~~ **or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one** product ~~candidates~~ **candidate. We may never succeed in these activities and, even if we do, we may never generate product revenue or revenues that** are **significant** ~~in early stages of research and development and we have suspended our~~ **or large enough to achieve profitability** ~~research and development activities for the near term while we focus on evaluating strategic alternatives for the Company~~ . **If** ~~As a result,~~ we are ~~not profitable and~~ **unable to generate sufficient revenue through the sale of any approved products, we may be unable to continue operations without additional funding. We** have incurred **significant net** losses in **each** ~~every reporting~~ period since ~~our inception~~ **we commenced operations in 2018. Our net loss** ~~as~~ **was $ 36** ~~Aquinox in 2003~~ . ~~For~~ **3 million for** the ~~years~~ - **year** ended December 31, ~~2022~~ **2023** ~~and 2021, we reported a net loss of $ 57~~ . **We expect** ~~6 million and $ 60. 7 million, respectively. As of December 31, 2022, we had an accumulated deficit since our inception as Aquinox of $ 451. 1 million. While we have taken measures~~ to ~~reduce our expenses in the near term, we~~ continue to incur significant ~~expenses related to our ongoing operations, including expenses relating to the wind down of our clinical program for NL- 201 and expenses related to our ongoing corporate restructuring, and are not currently moving any of our existing product candidates toward commercialization. We therefore expect to continue to have operating~~ losses for the foreseeable future. ~~If we are able~~ **Our operating expenses and net losses may fluctuate significantly from quarter** to ~~complete a strategic transaction~~ **quarter and year to year. We anticipate** that **our expenses** will **increase substantially if** ~~allow us to resume research~~ and **as we: • advance our existing and future programs through preclinical and clinical** development ~~activities~~ , ~~we may resume our work~~ **including expansion into additional indications; • seek** to identify **additional programs** ~~, acquire,~~ and **additional** ~~conduct research and development of future~~ product candidates ~~,~~ **; • continue to develop our gene therapy product candidate pipeline**

and ~~potentially begin~~ **our EXACT platform; • maintain, expand, enforce, defend and protect our intellectual property portfolio; • seek regulatory and marketing approvals for product candidates; • seek to identify, establish and maintain additional collaborations and license agreements, including those which may enhance the biodistribution and delivery of our product candidates; • ultimately establish a sales, marketing and distribution infrastructure** to commercialize any ~~future~~ **biological** products **for which we may obtain marketing approval, either by ourselves or in collaboration with others; • generate revenue from commercial sales of products for which we receive marketing approval; • hire additional personnel, including research and development, clinical and commercial; • add operational, financial and management information systems and personnel to support further expansion and operation as a public company; • acquire or in-license products, intellectual property and technologies which may enhance our current technology; and • establish commercial- scale cGMP capabilities through our own or third- party manufacturing facilities. In addition, our expenses will increase if, among other things, we are required by the FDA or other regulatory authorities to perform trials or studies in addition to, or different than, those** that ~~may achieve regulatory~~ **we currently anticipate, there are any delays in completing our clinical trials or the development of any product candidates, or there are any third- party challenges to our intellectual property or we need to defend against any intellectual property- related claim. Even if we obtain marketing** approval **for, and are successful in commercializing, one or more product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional programs and / or to expand the approved indications of any marketed product**. We may encounter unforeseen expenses, difficulties, complications, delays ~~,~~ and other unknown factors that may adversely affect our **business** ~~financial condition~~. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate ~~revenues~~ **revenue**. Our **failure** ~~prior losses and expected future losses have had, and will continue~~ to ~~have, an adverse effect on our financial condition. If we are unable to bring any of our product candidates or future product candidates through full clinical trials for any reason, or if such product candidates or future product candidates do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never~~ become profitable **would decrease**. ~~Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. The continued listing standards of the Nasdaq Stock Market, or~~ **our** ~~Nasdaq, require, among other things, that the minimum bid price of a listed company' s stock be at or above $ 1. 00. If the closing minimum bid price is below $ 1. 00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with Nasdaq' s listing rules and, if it does not regain compliance within the grace period, will be subject to delisting. On October 26, 2022, we received a notice from the Nasdaq Listing Qualifications Department notifying us that for 30 consecutive trading days, the bid price of our common stock had closed below the minimum $ 1. 00 per share requirement. In accordance with Nasdaq' s listing rules, we were afforded a grace period of 180 calendar days, or until April 24, 2023, to regain compliance with the bid price requirement. In order to regain compliance, the bid price of our common stock must close at a price of at least $ 1. 00 per share for a minimum of 10 consecutive trading days. If we fail to regain compliance by April 24, 2023, we may be eligible for a second 180 day compliance period, provided that, on such date, we meet the continued listing requirement for market~~ value ~~of publicly held shares and all other applicable Nasdaq listing requirements (other than the minimum closing bid price requirement) and we provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. Such extension of the grace period would be subject to Nasdaq' s discretion, and there can be no guarantee that we would be granted an~~ **and could impair** ~~extension. We cannot provide any guarantee that we will regain compliance during the grace period or~~ **our ability** ~~be able~~ to **raise capital,** maintain ~~compliance with Nasdaq' s listing requirements in the future. If we are not able to regain compliance during the grace period, or~~ **our research and development efforts** ~~any extension of the grace period for which we may be eligible~~, **expand** ~~our common stock will be subject to delisting. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or~~ **our business and /** ~~private sale of equity securities, would significantly affect the ability of investors to trade our~~ **or** ~~securities and would negatively affect the~~ **continue our operations. A decline in our** value ~~and liquidity of our common stock. Delisting~~ could also **cause you to** ~~have other negative results, including the potential loss~~ **lose** ~~of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. Since we became Neoleukin Therapeutics, Inc., our operations have been primarily limited to organizing and staffing our company, acquiring product and technology rights, discovering and developing novel de novo proteins, and undertaking preclinical studies and early clinical development activities. We have not yet obtained regulatory approval for any product candidate. In addition, in November 2022 and March 2023, we announced corporate restructurings which will result in a wind- down of the clinical trial for our first product candidate, NL- 201, the suspension of our research and development activities, and a significant reduction in our workforce with the intention of focusing on evaluation of a potential strategic alternatives, which may include a sale, merger, divestiture of assets, licensing or other strategic transaction. Consequently, evaluating our performance, viability or possibility of future success will be more difficult than if we had a longer operating history or approved products on the market. To date, we have not generated any revenues from commercial product sales, or otherwise. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize any products that we may develop, in- license, or acquire in the future. Even if we can successfully achieve regulatory approval for any product candidates or future product candidates, we do not know when any of these products will generate revenue from product sales for us, if at~~ all ~~. Our ability to generate revenue from any of our~~ **or** ~~product candidates or future product candidates also depends on several additional factors, including our or any future collaborators' ability to: • complete development activities, including the necessary clinical trials; • complete and submit Biologics License Applications, or BLAs, to the U. S. Food and Drug Administration, or FDA, and obtain regulatory approval for indications for which there is a commercial market; • complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities; • set a commercially viable price for our products; • establish and maintain supply and manufacturing relationships with third~~

parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply; • develop a commercial organization capable of sales, marketing, and distribution for any products for which we obtain marketing approval and intend to sell ourselves in the markets in which we choose to commercialize on our own; • find suitable distribution partners to help us market, sell, and distribute our approved products in other markets; • obtain coverage and adequate reimbursement from third- party - **part of** payors, including government and private payors; • achieve market acceptance for our **your** products, if any; • establish, maintain, and protect our intellectual property rights; and • attract, hire, and retain qualified personnel. In addition, because of the numerous risks and uncertainties associated with biological product development, any future product candidates may not advance through development or achieve the endpoints of applicable clinical trials. Therefore, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or trials in addition to those that we initially anticipate for any future product candidate. Even if we can complete the development and regulatory process for any product candidates or future product candidates, we anticipate incurring significant costs associated with commercializing these products. Even if we can generate revenues from the sale of any product candidates or future product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations. We will require additional capital to finance our operations which may not be available to us on acceptable terms, or at all. If we fail to obtain necessary financing, we may be unable to complete the development and potential commercialization of future product candidates. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. Our operations have consumed substantial amounts of cash since inception. If we identify and advance any current or future product candidates into clinical trials and launch and commercialize any product candidates for which we receive regulatory approval, we expect research and clinical development expenses, and our selling, general and administrative expenses to increase substantially. In connection with our current strategic initiatives, we believe that our existing cash, cash equivalents, and short- term investments - **investment** will be sufficient to fund our operating requirements through at least 12 months following the filing date of this Form 10- K. However, circumstances may cause us to consume capital more rapidly than we anticipate. If we are successful in completing a strategic transaction and able to resume our research and development activities, we will require additional capital for the further development and potential commercialization of future product candidates and may also need to raise additional funds to pursue a more accelerated development of future product candidates. If we seek to secure additional financing, fundraising efforts may divert our management from our day- to- day activities, which may adversely affect our ability to develop and commercialize future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to: • seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; • relinquish, or license on unfavorable terms, our rights to any future product candidates that we otherwise would seek to develop or commercialize ourselves; or • significantly delay, scale back, or discontinue the development or commercialization of any of our future product candidates or cease operations altogether. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results, and prospects. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward- looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this " Risk Factors " section. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available capital resources sooner than we currently expect. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: • our ability to identify or acquire additional product candidates for development; • the initiation, progress, timing, costs, and results of clinical trials for any future product candidates; • the estimated costs for discontinuing the development of NL- 201; • the clinical development plans we establish for any future product candidates; • if we in- license or acquire product candidates from third parties, the cost of in- licensing or acquisition; • the achievement of milestones and our obligation to make milestone payments under our present or any future in- licensing agreements; • the number and characteristics of product candidates that we discover, or in- license and develop; • the outcome, timing, and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect; • the cost to establish, maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patent claims and maintaining and enforcing other intellectual property rights; • the effects of global macroeconomic trends, including supply chain disruptions, inflationary pressures, unemployment rates and impacts of a potential market recession, on our business and financial results; • the effect of competing technological and market developments; • the costs and timing of the implementation of commercial- scale outsourced manufacturing activities; and • the costs and timing of establishing sales, marketing, distribution, and pharmacovigilance capabilities for any product candidates for which we may receive regulatory approval in territories where we choose to commercialize products on our own. If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our business, results of operations, financial condition and cash flows, and future prospects could be materially adversely affected . Risks Related to Discovery, Development , and Commercialization Product candidates in early stages of development may fail in development or suffer delays that materially and adversely affect their commercial viability. If we are unable to complete development of, or commercialize our product

candidates, or experience significant delays in doing so, our business will be materially harmed. Any product candidates that we have are in the early stages of development efforts. We **face competition** have no products on the market, we have elected to discontinue development of NL-201, we have suspended development of all of our remaining product candidates, which are still in drug discovery stages, and we may not ever obtain regulatory approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA, and have significantly reduced our clinical trial team in connection with the discontinuation of development of NL-201. Before obtaining regulatory approval for the commercial distribution of any future product candidates, we must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Moreover, our development portfolio consists of targets and programs that are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development, and in March 2023 we suspended development of all of our current product candidates to focus on evaluation of strategic alternatives for the Company while reducing operating costs in the near te. If we are able to resume development, or if we are able to acquire or in-license additional product candidates, but we do not receive regulatory approvals for clinical testing and commercialization of such product candidates, we may not be able to continue our operations. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any issues that cause or require us to delay or abandon preclinical or clinical trials or delay and / or prevent regulatory approval of or our ability to commercialize product candidates, including: • preclinical study results showing the product candidate to be less effective than desired or to have harmful or problematic side effects; • negative or inconclusive results from **entities** our clinical trials or the clinical trials of others for product candidates similar to ours; • product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologics similar to our product candidates; • a failure to demonstrate that the dose for the product candidate has been optimized; • the inability of third-party manufacturers to successfully manufacture our products or to meet regulatory specifications; • inability of any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials or commercial sales; • delays in submitting INDs or comparable foreign applications, or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced; • conditions imposed by the FDA, the European Medicines Agency, or EMA, or other applicable regulatory authorities regarding the scope or design of our future clinical trials; • delays in enrolling patients in clinical trials for future product candidates; • high drop-out rates of patients in our future clinical trial patients; • inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our future clinical trials; • inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials; • supply chain disruptions that may impact our ability to obtain materials for research and development, preclinical or future clinical testing or significantly increase our costs; • greater than anticipated costs of development, including preclinical studies and clinical trials; • manufacturing costs, formulation issues, pricing or reimbursement issues or other factors that no longer make a product candidate economically feasible; • harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials; • failure to demonstrate a benefit-risk profile acceptable to the FDA, EMA, or other applicable regulatory authorities; • unfavorable inspection and review by the FDA, EMA, or other applicable regulatory authorities of one or more clinical trial sites or manufacturing facilities used in the testing and manufacture of any of our product candidates; • failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all; • delays and changes in regulatory requirements, policy, and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or • varying interpretations of our data by the FDA, EMA, or other applicable regulatory authorities. Our inability to complete development of, or commercialize our product candidates, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations, and prospects. Further, cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for advanced cancers, i. e. third-line or beyond. When cancer is detected early enough, first-line therapy, usually chemotherapy, surgery, radiation therapy, immunotherapy, hormone 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 is not effective. We expect that our product candidates will initially be targeted to second-or third-line patients, and that if those product candidates prove to be sufficiently beneficial in those initial trials, we would expect to seek subsequent approval in earlier lines of therapy. Any product candidates we develop, even if approved, may not be successfully approved for earlier lines of therapy, and, prior to any such approvals, we will likely have to conduct additional clinical trials, which are often very lengthy, expensive, and have a significant risk of failure. Our business is heavily dependent on our ability to obtain regulatory approval of, and then successfully launch and commercialize, our product candidates. We have invested a significant portion of our efforts and financial resources in the development of advanced computational algorithms and other methods, including machine learning for the design of functional de novo proteins with an initial focus on key cytokine mimetics, which we refer to as Neoleukin de novo cytokine mimetics. In the fourth quarter of 2022, based on a review of the preliminary data, the expected benefit to risk ratio for patients, and recent developments in the field of IL-2 therapeutics, we made a strategic decision to discontinue development for our lead product candidate, NL-201, and undertake a corporate restructuring to focus investment on the next generation of de novo protein design. As a result, all product candidates we have pursued in recent months are in early stages of development. In March 2023, our Board of Directors approved a further restructuring of the Company which resulted in the near-term suspension of all research and development activities to focus on a review of strategic alternatives. Our ability to generate commercial product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. If we are able to bring any of our product candidates to clinical trial, they may not be successful in those trials or, even if they are, they may not

receive regulatory approval in a timely manner, or at all. Regulatory agencies, such as an FDA Advisory Committee or similar authority, may recommend non- approval or place restrictions on approval, which may also increase costs and delay commercialization. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process. For example, the Oncology Center of Excellence within the FDA has recently advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which maximizes not only the efficacy of a drug but the safety and tolerability as well. This may require sponsors to spend additional time and resources to further explore a product candidate' s dose- response relationship to facilitate optimum dose selection. Other recent Oncology Center of Excellence initiatives include Project FrontRunner, a framework for identifying candidate drugs for initial clinical development in the earlier lines of therapies rather than only after exhausting available treatment options. We are considering these policy changes as they relate to our programs. Regulatory authorities may approve a product candidate for targets, disease indications, or patient populations that are not as broad as we intended or desired, approve more limited indications than requested, or require distribution restrictions or strong safety language, such as contraindications or boxed warnings. Regulatory authorities may also require Risk Evaluation and Mitigation Strategies, or REMS, or the performance of costly post- marketing clinical trials. Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved. We expect to seek regulatory approval to commercialize any future product candidates we may bring forward for clinical development both in the United States and in selected foreign countries. In order to market and sell our product candidates in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. 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. The approval procedure varies among countries and can involve additional testing. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may be required to expend significant resources to obtain regulatory approval, which may not be on a timely basis or successful at all, and to comply with ongoing regulations in these jurisdictions. The success of our Neoleukin design process and our future product candidates will depend on many factors, including the following: • successful completion of necessary preclinical studies to enable the initiation of clinical trials; • successful enrollment of patients in, and the completion of, our clinical trials; • obtaining adequate financing to perform the expensive clinical development programs anticipated for approval; • receiving required regulatory authorizations for the development and approvals for the commercialization of our product candidates; • establishing and maintaining arrangements with third- party manufacturers; • obtaining and maintaining patent and trade secret protection and non- patent exclusivity for our product candidates and their components; • enforcing and defending our intellectual property rights and claims; • achieving desirable therapeutic properties for our product candidates' intended indications; • launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with third parties; • acceptance of our product candidates, if and when approved, by patients, the medical community, and third- party payors; • achieving appropriate reimbursement, pricing, and payment coverage for our product candidates; • effectively competing with other therapies, including those that are currently in development; and • maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory approval. If we do not achieve any one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, we may be required to revise, pause, delay, or abandon the trials or our development efforts of one or more product candidates altogether, we may be required to have more restrictive labeling, or we may experience the delay or denial of regulatory approval by applicable regulatory authorities. We, applicable regulatory authorities, or IRBs, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early- stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Therapies involving cytokines have been known to cause side effects such as neurotoxicity and cytokine release syndrome, and there is no guarantee that these side effects can be avoided through de novo protein design. Further, de novo proteins are a new class of therapeutics that have **developed** not been tested in humans prior to our **or** initial Phase 1 clinical trial of NL **may develop programs for the diseases we plan to address with NGN** - **401** 201. De novo proteins can be substantially different from all known proteins and **NGN- 101** as a result it is unknown to what extent, if any, de novo proteins may produce immunologic reactions in patients. Immunologic reactions could substantially limit the effectiveness of the treatment, the duration of treatment, or represent safety risks. Additionally, if any of our **or other** product candidates receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the product outweigh its risks, which may include, among other things, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore,

if we or others later identify undesirable side effects caused by any of our products, several potentially significant negative consequences could result, including: • regulatory authorities may suspend or withdraw approvals of such product; • regulatory authorities may require additional warnings on the label of such product; • we may be required to change the way such a product is administered or conduct additional clinical trials; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer. Any of these developments could materially harm our business, financial condition, and prospects. 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. 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, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline. The success of our recent development programs depends primarily upon the ability to discover, develop, and commercialize a pipeline of product candidates using our Neoleukin de novo protein design process. Unlike traditional protein- based therapeutics that modify native proteins, our Neoleukin design process allows us to create new proteins from the ground up. Our design process uses advanced computational algorithms and methods to design functional de novo proteins that are hyper- stable, modifiable, and are designed to optimize desired intermolecular interactions and eliminate undesirable interactions. While we believe this approach will enable the development of product candidates that may offer unique therapeutic benefits, the scientific basis of our efforts to develop product candidates using our Neoleukin design process is ongoing and may not result in viable product candidates. While we had favorable preclinical study results related to NL- 201, and monotherapy data that demonstrated engagement of the target receptor, expected pharmacodynamic changes for a potent IL- 2 / IL- 15 agonist, and preliminary data that did not demonstrate significant immunogenicity even after multiple cycles of therapy, and in November 2022 we determined that the resources required to continue clinical development would be better applied to advancing the next generation of de novo immunotherapies. We may not be successful in moving any of our future product candidates into clinical development, and any product candidates that we are able to bring into clinical trials may subsequently be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing or make the product candidates unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for one or more programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Following the completion of the wind- down of our NL- 201 clinical trial, we will not have any product candidate currently being tested in a clinical trial, nor do we have near- term plans to commence any additional clinical trials. We have not tested any of our other product candidates in clinical trials. We may ultimately discover that our Neoleukin design process and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. Our product candidates may also be unable to remain stable in the human body for the period of time required for the drug to reach the target tissue, or they may trigger immune responses that inhibit the activity of the product candidate or that cause adverse side effects in humans. We may spend substantial funds attempting to mitigate these properties and may never succeed in doing so. In addition, product candidates based on our Neoleukin design process may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Our Neoleukin design process and any product candidates resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective, or harmful ways. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known, or extensively studied product candidates. Because the FDA has no prior experience with de novo proteins as therapeutics, we anticipate that this may increase the complexity, uncertainty, and length of the regulatory approval process for our product candidates. We or any future partners may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post- marketing testing requirements to maintain regulatory approval. If the products resulting from our Neoleukin design process and research programs prove to be ineffective, unsafe, or commercially unviable, our Neoleukin design process and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations, and prospects. Development of immunotherapies involves a lengthy and expensive process, with an uncertain outcome, and results of early studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any of our product candidates. Following the decision in November 2022 to discontinue development of NL- 201, all of our product candidates are now in preclinical or earlier development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex, and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and the outcome is inherently uncertain. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Failure can occur at any time during the clinical trial process, or we may decide, as we did with NL- 201, to stop development for strategic reasons at any time. The results of preclinical studies and early- stage clinical trials may not be predictive of the success of later- stage clinical trials, and differences in trial design between early- stage clinical trials and later- stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have

nonetheless failed to obtain marketing approval of their products. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier trials, and we could face similar setbacks. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products, and there can be no assurance that any of our clinical trials will ultimately be successful or support clinical development of our product candidates. Commencement of any future clinical trials for our product candidates is subject to finalizing the trial design and receiving approval from the FDA to proceed with clinical testing or similar approval from the EMA or other comparable foreign regulatory authorities. Even after we submit our IND or comparable submissions in other jurisdictions, if the FDA, EMA, or comparable foreign regulatory authorities disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, we may be required to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials. We may encounter substantial delays in the commencement or completion of our clinical trials, or may be required to terminate or suspend such trials, which could result in increased costs to us or delay or limit our ability to generate revenue, adversely affecting our commercial prospects. If we are able to move any of our product candidates to the clinical trial stage, we may experience delays in initiating or completing clinical trials or may experience numerous unforeseen events during, or as a result of, any such future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any future product candidates, including: • we may be unable to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to obtain regulatory authorizations to commence a clinical trial; • we may experience issues in reaching a consensus with regulatory authorities on trial design; • regulators or institutional review boards, ethics committees, FDA, EMA, or other applicable regulatory authorities, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • clinical trial sites may deviate from trial protocol or drop out of a trial; • clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, which in turn may cause us to decide, or regulators to require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs; • the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post- treatment follow- up at a higher rate than we anticipate; • our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; • we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks; • the cost of clinical trials of any of our product candidates may be greater than we anticipate; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial, or may be adversely impacted by global supply chain issues; • we may be unable to obtain or manufacture sufficient quantities of our product candidates for use in clinical trials; • reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates; and • we may fail to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other molecules in the same class as our product candidate. We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board, or the DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial or other reasons related to our overall business strategy. For example, prior to our discontinuation of development of NL-201, NL- 201 was subject to an FDA clinical hold, which was later lifted. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA, or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. Our product development costs will increase if we experience delays in clinical testing or obtaining marketing approvals. We do not know whether we will be able to bring any of our product candidates forward to clinical trial and, if we do, if any of our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly. If we experience delays or difficulties in the enrollment of patients in clinical trials, our future clinical development activities could be delayed or otherwise adversely affected. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the number and location of clinical sites we enroll, the

proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, CROs, and clinical trial sites to ensure the proper and timely conduct of our future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in future clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. If we are unable to enroll a sufficient number of patients for our future clinical trials, it would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing if needed. Preliminary, topline, and interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures, and such changes in the final data may be material. From time to time, we may publish preliminary or topline data from our recently terminated or future clinical trials, which is based on a preliminary analysis of then- available data. Those results and any related findings and conclusions are subject to change following a more comprehensive review of the more complete data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary or topline results that we report may differ from future results of the same studies or clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data we previously published. Results from prespecified interim analyses that we may conduct 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. As a result, preliminary and topline data and prespecified interim analyses should be viewed with caution until the final data are available. Adverse differences between preliminary, topline, or interim data and final data could significantly harm our reputation and business prospects. Failure to obtain regulatory approval would prevent any future product candidates from being marketed. In order to market and sell our products, we must obtain marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval differs substantially from jurisdiction to jurisdiction. In many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Approval by a single regulatory authority does not ensure approval by other regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities. A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our future product candidates by regulatory authorities, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline. Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of, and commercialization of, our future product candidates and affect the prices we may obtain. The regulations that govern, among other things, marketing approvals, coverage, pricing, and reimbursement for new drug products vary from country to country. 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 future product candidates, restrict or regulate post- approval activities, and affect our ability to successfully sell any product candidates for which we obtain marketing approval. In the United States in recent years, Congress has considered reductions in Medicare reimbursement for drugs administered by physicians. The Centers for Medicare and Medicaid Services, or CMS, the agency that administers the Medicare program, also has the authority to revise reimbursement rates and to implement coverage restrictions for drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of, and reimbursement for, any approved products, which in turn could affect the price we can receive for those products. For example, on September 9, 2021, the Biden administration published a wide- ranging list of policy proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices, disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the IRA in August 2022, which will, among other things, allow the U. S. Department of Health and Human Services, or HHS, to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high- expenditure single- source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the " donut hole " under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10 % of Part D enrollees' prescription costs for brand drugs below the out- of- pocket maximum, and 20 % once the out- of- pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance,

as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in establishing their own coverage polices and reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors. In March 2010, President Obama signed into law the Affordable Care Act in an effort to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. The Affordable Care Act, among other things, also expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program, imposed a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products, and enacted substantial provisions affecting compliance, which may affect our business practices with healthcare practitioners. Certain provisions of the Affordable Care Act have been subject to judicial and Congressional challenges to repeal or replace certain aspects of the Affordable Care Act. On June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued that the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the Affordable Care Act and in turn our business, prospects, financial condition, or results of operations. Other legislative measures impacting federal expenditures on health care may also have an adverse impact on our business. For example, on August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, triggering the legislation' s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year that went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension followed by reduction from May 1, 2020 through June 30, 2022 due to the COVID- 19 pandemic, unless additional Congressional action is taken. In addition, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have also been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. Furthermore, in the past few years there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, including Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer' s patient programs, and reform government program reimbursement methodologies for drug products. We cannot be sure whether additional legislative changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our future product candidates, if any, may be. In the United States, the European Union and other potentially significant markets for our future product candidates, government authorities and third- party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional coverage, pricing, and reimbursement controls in the European Union will put additional pressure on product coverage, pricing, reimbursement, and utilization, which may adversely affect our business, results of operations, financial condition, cash flows, and future prospects. These pressures can arise from various sources, including but not limited to, rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies, and pricing in general. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval. Laws and regulations governing international operations may preclude us from developing, manufacturing, and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs. As we expand our operations outside of the United States, we must comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We must also comply with U. S. laws applicable to the foreign operations of U. S. businesses and individuals, such as the Foreign Corrupt Practices Act, or FCPA. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. The FCPA prohibits any U. S. individual or business from paying, offering, authorizing payment, or offering anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in

obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti- bribery provisions of the FCPA are enforced primarily by the U. S. Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because in many countries hospitals are operated by the government, and therefore doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations, and executive orders also restrict the use and dissemination outside the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U. S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long- term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. Even if we are able to commercialize our future product candidates, the products may not receive coverage and adequate reimbursement from third- party payors, which could harm our business. Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers, health maintenance organizations, and third- party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our future product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. As a result, government authorities and other third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third- party payors may also seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what that level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product 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 comparable foreign regulatory authorities. Moreover, obtaining coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based in part on existing reimbursement amounts for lower cost drugs or may be bundled into the 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. Coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage and reimbursement determination process is often a time- consuming and costly process with no assurance that coverage and adequate reimbursement will be obtained or applied consistently. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition. We have never marketed a drug before. If we are able to identify and develop or acquire a product candidate that is ultimately approved for sale but are unable to establish an effective sales force and marketing infrastructure or enter into acceptable third- party sales and marketing or licensing arrangements, we may be unable to generate any revenue. We do not currently have an infrastructure for the sales, marketing, and distribution of pharmaceutical drug products, and the cost of establishing and maintaining such an infrastructure may exceed the cost- effectiveness of doing so. In addition, following the decision to discontinue development ofNL- 201 in November 2022, we do not have any product candidates in clinical development. If we are able to successfully advance any of our future product candidates through clinical development to approval by the FDA and comparable foreign regulatory authorities, we will need to either build our sales,

~~marketing and distribution operations, including managerial and other non- technical capabilities, or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that have extensive and well- funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing team may not be successful in commercializing our product candidates, which would negatively affect our ability to generate revenue. We may not be successful in our efforts to use our Neoleukin design process to expand our pipeline of product candidates and develop marketable products. The success of our business depends in part upon our ability to discover, develop, and commercialize products based on our Neoleukin design process, which may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we must choose the product candidates on which we focus our research and development efforts, which may require us to forgo or delay pursuit of opportunities with other product candidates that may ultimately have greater commercial potential. For instance, prior to November 2022, we were primarily focused on developing our lead product candidate, NL- 201, and invested significant resources in the preclinical and Phase 1 clinical trial for that product candidate, but ultimately decided that our limited resources would be better spent on early stage research of the next generation de novo protein design and so elected to discontinue development of NL- 201 even though that product candidate had demonstrated on target activity in reviews of preliminary data. Our resource allocation decisions may require us to make strategic decisions, which in turn may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We face substantial competition, including companies developing novel treatments and technology platforms in oncology. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected~~ . The development and commercialization of ~~drugs~~ **biological products** is highly competitive. ~~Our~~ **If approved, NGN- 401 and NGN- 101 or other** product candidates ~~, if approved,~~ will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. ~~Most~~ **We compete with a variety** of **multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing** ~~our~~ **or** ~~competitors~~ **will compete against in the future** have significantly greater **financial** resources **and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products** than we do ~~and we may not be able to successfully compete~~ . ~~We~~ **Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also** compete with **us in recruiting** ~~a variety of multinational biopharmaceutical companies, specialized biotechnology companies,~~ and ~~emerging biotechnology companies~~ **retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials** , as well as ~~with~~ **in acquiring** technologies **complementary to, or necessary for, NGN- 401** and **NGN- 101 or other** product candidates **. As described in** ~~being developed at academic institutions, governmental agencies, and other~~ **the** ~~public and private research institutions. Our~~ **section above entitled " Business — Competition ", our** competitors have developed, are developing ~~,~~ or ~~will~~ **may** develop **programs or clinical stage** ~~product~~ **products** ~~candidates and processes~~ competitive with **NGN- 401** ~~our~~ **or NGN- 101 or other earlier stage** product candidates ~~and processes~~ . Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments ~~, including those based on novel technology platforms that enter the market. We believe that a significant number of products are currently under development and may become commercially available in the future~~ for **Rett syndrome or** ~~the treatment of conditions~~ for **CLN5 Batten disease** ~~which we are trying, or may try, to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical, and interleukin and immunoregulatory therapeutics fields. Competition from many sources exists or may arise in the future. Our competitors include larger and better funded biopharmaceutical, biotechnological, and therapeutics companies, including companies focused on oncology therapeutics, as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions. Some of these companies are well- capitalized and, in contrast to us, have significant clinical experience, and may include our future partners. In addition, these companies compete with us in recruiting scientific and managerial talent~~ . Our success will depend partially on our ability to develop and commercialize ~~therapeutics~~ **products** that ~~are safer~~ **have a competitive safety, efficacy or potency, dosing** and /

or presentation profile ~~more effective than competing products~~. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective ~~,~~ or **potent, have a more attractive or less invasive dosing profile or presentation or are** less expensive than **any products we may develop, or if competitors develop competing products or if biosimilars enter the market more quickly than we are able to, if we are able to at all, and are able to gain market acceptance. NGN- 401, NGN- 101 and our other programs are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize, our product candidates, or experience significant delays in doing so, our business will be materially harmed. We have no products on the market and NGN- 401 and NGN- 101 are in the early stages of clinical development, while our other programs are in early stages of preclinical development. As a result, we expect it will be many years before we commercialize these product candidates and ultimately may not be successful in commercializing any of our product candidates. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, our lead product candidate NGN- 401 or other product candidates, including NGN- 101, either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any product candidates. We have limited experience as a company in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or comparable foreign regulatory authorities. We have not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Before obtaining regulatory approval for the commercial distribution of product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety, purity and efficacy or potency in humans of such product candidates. We or our collaborators may experience delays in initiating or completing clinical trials, and also may experience unforeseen events during, or as a result of, any current or future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize NGN- 401 or NGN- 101 or any other product candidates, including: • regulators or institutional review boards (“ IRBs ”), the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • the observation of an actual or suspected unexpected serious adverse reaction, serious adverse events, or adverse events of special interest could result in a partial or complete clinical hold for an unpredictable length of time, delay or halt future enrollment, require increased staggering between patient dosing, require dose reductions that could adversely affect the anticipated efficacy or potency product profile, or require a program discontinuation; • clinical trial sites may fail to meet enrollment targets, may deviate from trial protocol, or may experience patients dropping out of a trial; • clinical trials of any product candidates may fail to show safety or efficacy or potency, or produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs; • the number of subjects required for clinical trials of any of our product candidates may be larger than we anticipate, especially if the effect size observed in future clinical data from a Phase 1 / 2 clinical trial is small or is difficult to ascertain relative to natural history as a comparator, or if regulatory authorities require completion of a sham- controlled clinical trial; • enrollment in clinical trials may be slower than we anticipate or subjects may drop out of clinical trials or fail to return for post- treatment follow- up at a higher rate than we anticipate; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; • we may elect to, or regulators, independent data safety monitoring boards (“ DSMBs ”), IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research or trials, or delay further dosing of subjects in clinical trials, for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks; • the cost of clinical trials of any of our product candidates may be greater than we anticipate; • the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial; • our inability to manufacture sufficient quantities of our product candidates for use in clinical trials; • reports from clinical testing of other therapies may raise safety or efficacy or potency concerns about our product candidates; • our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other therapies in the same class as our product candidates; and • the FDA or other regulatory authorities may require us to submit additional data, such as long- term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial. Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND or, if commenced in other jurisdictions, acceptance by the comparable foreign regulatory agency of a similar application, as well as finalizing the trial design. In the event that the FDA or applicable foreign regulatory agency requires us to complete additional preclinical studies, or we are required to satisfy other regulatory requests prior to commencing clinical trials, the start of our clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other**

jurisdictions, including the United Kingdom (“ UK ”), Australia and the European Union. We may not have the financial resources to continue development of, or to modify existing collaborations or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, NGN- 401 or NGN- 101 or any other product candidates. We or our current or future collaborators' inability to complete development of, or commercialize, NGN- 401 or NGN- 101 or any other product candidates or significant delays in doing so, could have a material and adverse effect on our business, financial condition, results of operations and prospects. We currently utilize adeno- associated virus serotype 9 (“ AAV9 ”) capsid for delivery of therapeutic transgenes to deliver our product candidates, which may limit the safety, purity, and efficacy or potency of such product candidates. Our current approach is to identify, develop and commercialize gene therapy product candidates using an AAV9 capsid for delivery of therapeutic transgenes to certain kinds of cells. Although AAV9 has been tested in numerous clinical trials and is an approved serotype for one gene therapy product, we cannot be certain that our AAV9 product candidates will successfully advance through preclinical studies and clinical trials, or that ~~the~~ they will not cause significant adverse events or toxicities. We also cannot be certain that we will be able to avoid triggering toxicities in our future preclinical studies or clinical trials or that our chosen routes of administration to deliver such therapies will not cause unforeseen side effects or other challenges. Although AAV9 has been shown to facilitate biodistribution and cell transduction to the central nervous system (“ CNS ”), the potentially limited levels of AAV9 transduction of cells in the CNS and certain retinal cells may limit the potential efficacy or potency of any of our product candidates, including NGN- 401 and NGN- 101. We intend to identify and develop novel gene therapy product candidates, which makes it difficult to predict the time, cost and potential success of product candidate development. A key part of our business strategy is to identify and develop additional product candidates. As such, our future success depends on the successful development of novel therapeutic approaches, including by utilizing our EXACT technology or other gene regulation technology. Our preclinical research and clinical trials may initially show promise in identifying potential product candidates, yet fail to yield product candidates for a number of reasons. For example, although EXACT is designed to deliver therapeutic levels of transgene while avoiding off- target effects, there can be no assurance that any EXACT gene regulation will result in product candidates that are shown in clinical trials to be safe, pure, and effective or potent. To date, very few products that utilize gene transfer have been approved in the United States, Europe or other markets, and no products have been approved using our EXACT (Expression Attenuation via Construct Timing) technology. There have been a limited number of clinical trials of gene transfer technologies, with only very few product candidates ever approved by the FDA or comparable foreign regulatory authorities. As a result, it is difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our approach to gene therapy will result in the identification, development, and regulatory approval of any product candidates, or that other gene therapy programs will not be considered better or more attractive. There can be no assurance that any development problems we experience in the future related to our current gene therapy approaches or product candidates or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Research programs to identify new product candidates require substantial technical, financial, and human resources. If we are unable to identify suitable gene therapy product candidates for preclinical and clinical development, we may not be able to successfully implement our business strategy, and may have to delay, reduce the scope of, suspend or eliminate one or more of our product candidates, clinical trials or future commercialization efforts, which would negatively impact our financial condition. The disorders we seek to treat have low prevalence and it may be difficult to identify and enroll patients with these disorders. If we experience delays or difficulties in the enrollment and / or maintenance of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. Successful and timely completion of clinical trials will require that we enroll and maintain a sufficient number of patients. Patient enrollment is affected by many factors, including the size and nature of the patient population and competition for patients with other trials. Genetic diseases generally, and especially the rare diseases for which some of our current product candidates are targeted, have low incidence and prevalence. For example, we estimate global incidence of all 13 subtypes of Batten disease is approximately one in 100, 000 live births, and the CLN5 Batten disease incidence, which is included in this estimate, is estimated to be even lower. Accordingly, it may be difficult for us to identify and timely recruit a sufficient number of eligible patients to conduct our clinical trials. Further, any natural history studies that we or our collaborators may conduct may fail to provide us with patients for our clinical trials because patients enrolled in the natural history studies may not be good candidates for our clinical trials, or may choose to not enroll in our clinical trials. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product 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, the European Medicines Agency (“ EMA ”) or other foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including: • the eligibility criteria for the trial in question; • the timely diagnosis of disease to meet such eligibility criteria; • the size of the patient population and process for identifying patients; • the perceived risks and benefits of the product candidate in the trial, especially by clinician experts and patient advocacy organizations, including relating to AAV9- based gene therapy and intracerebral spinal fluid delivery system; • the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials; • the willingness of caregivers to enroll their children in our clinical trials; • the efforts to facilitate timely enrollment in clinical trials; • potential disruptions caused by pandemics or other public health crises, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be

implemented, and other factors; • the patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; and • the proximity and availability of clinical trial sites for prospective patients. Even if we are able to enroll a sufficient number of patients in our clinical trials, we may have difficulty maintaining enrollment of such patients. Our inability to enroll or maintain a sufficient number of patients would result in significant delays in completing clinical trials or receipt of marketing approvals and increased development costs, or may require us to abandon one or more clinical trials altogether. We are substantially dependent on the success of our most advanced product candidates, NGN- 401 and NGN- 101, and our ongoing and anticipated clinical trials of such candidates may not be successful. Our future success is substantially dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our most advanced product candidates, NGN- 401 and NGN- 101. We are investing a majority of our efforts and financial resources into the research and development of these candidates. We are conducting a Phase 1 / 2 clinical trial of NGN- 401 in patients with Rett syndrome and a Phase 1 / 2 clinical trial of NGN- 101 in patients with CLN5 Batten disease. If topline results from our Phase 1 / 2 clinical trial of NGN- 401 are successful, we anticipate initiating a pivotal clinical trial, pending future regulatory feedback on various aspects of development such as the pivotal trial design and manufacturing related requirements. If topline results from our Phase 1 / 2 clinical trial of NGN- 101 are successful, we anticipate initiating a pivotal clinical trial or expanding the current Phase 1 / 2 clinical trial, pending future regulatory feedback on various aspects of development, such as the Phase 3 clinical trial design and manufacturing related requirements. NGN- 401 and NGN- 101 will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate revenues from product sales, if any. We are not permitted to market or promote these product candidates, or any other product candidates, before we receive marketing approval from the FDA and / or comparable foreign regulatory authorities, and we may never receive such marketing approvals. The success of NGN- 401 and NGN- 101 will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we cannot guarantee that we will ever be able to generate revenue through the sale of these candidates, even if approved. If we are not successful in commercializing NGN- 401 or NGN- 101, or are significantly delayed in doing so, our business will be materially harmed. Our programs are focused on the development of therapeutics **for patients with neurological diseases, which is a rapidly evolving area of science, and the approach** we **are taking to discover and** develop ~~. Many of~~ **product candidates is novel and may never lead to approved** ~~our~~ **or** ~~competitors~~ **marketable products. The discovery and development of therapeutics for patients with neurological diseases is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our preclinical work, that our programs** have ~~significantly greater financial~~ **the potential to be disease- modifying therapies** , ~~technical, manufacturing, marketing, sales, and supply resources~~ **clinical results may not confirm this hypothesis or may only confirm it** ~~or~~ **for** ~~experience~~ **certain alterations or certain indications. The patient populations for our product candidates are limited to those with specific neurological diseases. We cannot be certain** ~~than~~ **that** ~~we have. If we~~ **the patient populations for each specific disease will be large enough to allow us to** successfully obtain approval **and commercialize our product candidates and achieve profitability. Further, both our Phase 1 / 2 clinical trial of NGN- 401 and Phase 1 / 2 clinical trial of NGN- 101 will involve a small patient population. Because of the small sample sizes, the results of these trials may not be indicative of results of future clinical trials. If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of NGN- 401** ~~for~~ **or NGN- 101 or** any **other** product ~~candidate~~ **candidates 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. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and** will **be** ~~face competition~~ 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, the commercialization of NGN- 401 or NGN- 101 or any other product candidates may be delayed or never achieved and, as a result, our stock price may decline. Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies, which are a lengthy, time consuming and expensive process with risk of high failure. The length of time of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses. However, after conducting preclinical studies, we must then conduct extensive clinical trials to demonstrate the safety, purity, and efficacy or potency of our product candidate in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all. For example, we depend on the availability of NHPs to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development. There is**

currently a global shortage of NHPs available for biological product development. This could cause the cost of obtaining NHPs for our future preclinical studies to increase significantly and, if the shortage continues, could also result in delays to our development timelines. Furthermore, failure can occur at any time during the preclinical study or clinical trial process, and the outcome of preclinical studies and early- stage clinical trials may not be predictive of the success of later clinical trials, especially as our initial clinical trials do not contain a control arm. In addition, we have designed our initial clinical trials with relatively small cohorts before expanding in size and dosing in subsequent cohorts. If safety issues arise in an early cohort, we may be delayed or prevented from dose escalating or subsequently expanding into larger trial cohorts. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many **companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Earlier gene therapy clinical trials conducted by others also utilized AAV vectors. However, these studies should not be relied upon as evidence that our planned clinical trials will succeed. In addition, we expect to rely on patients to provide feedback on measures, which are subjective and inherently difficult to evaluate. These measures can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient, and from patient to patient and from site to site within a clinical trial. We cannot be sure that the FDA or comparable foreign regulatory authorities will agree with our clinical development plan. We are conducting a Phase 1 / 2 clinical trial of NGN- 401 in patients with Rett syndrome and a Phase 1 / 2 clinical trial of NGN- 101 in patients with CLN5 Batten disease. If the FDA or comparable regulatory authorities requires us to conduct additional trials or enroll additional patients, our development timelines may be delayed. We cannot be sure that submission of an IND application, clinical trial application (" CTA ") or similar application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to require us to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among** different **CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; difficulties in patient enrollment in our clinical trials for a variety of reasons; delays in manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA' s or any other regulatory authority' s good clinical practices (" GCPs ") or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to larger- scale facilities operated by a CDMO and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us. We could also encounter delays if a clinical trial is placed on clinical hold, suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, the competent authorities and / or ethics committees of the UK, Australia, EU Member States or other regulatory authorities, if a clinical trial is recommended for suspension or termination by the DSMB or equivalent body for such trial, or on account of changes to federal, state, or local laws. If we are required to conduct additional clinical trials or other testing of NGN- 401 or NGN- 101 or any other product candidates beyond those that we contemplate, if we are unable to successfully complete clinical trials of NGN- 401 or NGN- 101 or any other product candidates, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. In addition, even if we are able to successfully complete clinical trials for NGN- 401 or NGN- 101, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. This is particularly true for clinical trials in very rare diseases, such as with our Phase 1 / 2 clinical trial of NGN- 101 for the treatment of CLN5 Batten disease and Phase 1 / 2 clinical trial of NGN- 401 for the treatment of Rett syndrome, where the very small patient population makes it difficult to conduct two traditional, adequate and well- controlled studies. In such cases, the FDA or comparable foreign regulatory authorities are often required or permitted to exercise flexibility in approving therapies for such diseases, but obtaining flexibility is uncertain and may never occur. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in the other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or applicable regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Preliminary, " topline " or interim data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures. From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also**

make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. Preliminary, interim or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously disclosed. These preliminary, interim or topline data 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 or as patients from our clinical trials continue other treatments. As a result, preliminary, interim and topline data should be viewed with caution until final data are available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or commercialization of a particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, interim or topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, NGN- 401 or NGN- 101 or any other product candidate may be harmed, which could harm our business, operating results, prospects or financial condition. In addition, differences between preliminary, interim or topline data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. Our current or future clinical trials may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval or limit commercial potential or market acceptance of any of NGN- 401 or NGN- 101 or any other product candidates or result in potential product liability claims. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While our Phase 1 / 2 clinical trials have not shown any such characteristics to date, we have not yet completed those clinical trials. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, patients may be harmed, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether, including NGN- 401 or NGN- 101. We, the FDA, EMA, or other applicable regulatory authorities, or an IRB, may require suspension of any clinical trials of NGN- 401 or NGN- 101 or any other product candidates at any time for various reasons, including a finding that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products developed in the biotechnology industry that initially showed therapeutic promise in early- stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude a product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of an approved product due to its tolerability versus other therapies. In addition, as gene replacement has a potentially life- long activity, with no ability to withdraw the product as with other treatment modalities, this profile could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Treatment- emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with NGN- 401 or NGN- 101 or any other product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from NGN- 401 or NGN- 101 or any other product candidates may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm our business, financial condition, results of operations and prospects significantly. In addition, even if we successfully advance NGN- 401 or NGN- 101 or any other product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of follow up to such product candidates. As a result, we cannot be assured that adverse effects of NGN- 401 or NGN- 101 or any other product candidates will not be uncovered when a significantly larger number of patients are exposed to such product candidate after approval, or a significantly longer follow up post- dosing is obtained as part of regulators' recommendations for long- term follow up of clinical study subjects treated with gene therapy. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi- year period. We have expended substantial efforts and costs testing our EXACT technology in preclinical studies of NGN- 401, including completing toxicology studies prior to the FDA providing clearance of the IND for NGN- 401. However, we cannot guarantee that significant adverse effects will not be seen in clinical trials for NGN- 401, which could result in clinical holds, delays, suspension or withdrawal of our IND. If any of the foregoing events occur or if NGN- 401 or NGN- 101 or any other product candidates prove to be unsafe, our entire pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects. We may expend our limited resources to pursue a particular product candidate, such as NGN- 401 or NGN- 101, and fail to capitalize on candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we intend to focus our research and development efforts on certain selected product candidates. For example, we are initially allocating significant resources to our most advanced product candidates, NGN- 401 and NGN- 101. As a result, we may forgo or delay pursuit of opportunities with other potential candidates that may 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 for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that 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 candidate. Even if regulatory approval is obtained, any approved products resulting from NGN- 401 or NGN- 101 or any other product candidate may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products. Even if regulatory approval is obtained for NGN- 401 or NGN- 101 or any other product candidates, our product candidates may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. There is currently one FDA- approved product and multiple other product candidates in various stages of development for the treatment of Rett syndrome. Market participants with significant influence over acceptance of new treatments, such as clinicians and third- party payors, may not adopt a gene therapy replacement with a target product profile such as that of NGN- 401 or NGN- 101 or for their targeted indications, and we may not be able to convince the medical community and third- party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of NGN- 401 or NGN- 101 or any other product candidates will depend on many factors , including ~~the safety and effectiveness of~~ factors that are not within our control. Sales of biological products also depend on the willingness of clinicians to prescribe the treatment. We cannot predict whether clinicians , clinicians' organizations, hospitals, ~~the~~ other ~~ease~~ healthcare providers, government agencies or private insurers will determine that any of our approved products are safe, therapeutically effective or potent, cost effective or less burdensome as compared with competing treatments. If NGN- 401 or NGN- 101 or any other product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product and may not become or remain profitable. We have never commercialized a product candidate and may lack the necessary expertise, personnel and resources to successfully commercialize a product candidate on our own or together with suitable collaborators. We have never commercialized a product candidate and currently have no sales force, marketing or distribution capabilities. To achieve commercial success for a product candidate, we may opt to license such product candidate to others, in which case we may rely on the assistance and guidance of our collaborators on that license arrangement. For a ~~products~~ product candidate for ~~can be administered and the extent to~~ which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party. Factors that may affect our ability to commercialize a product candidate, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidate, ensuring regulatory compliance of our company, employees and third ~~patients~~ parties ~~accept relatively new routes~~ under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time- consuming and could delay the launch of ~~administration~~ a product candidate upon approval. Moreover , we may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of an approved product candidate, we may not generate revenues from ~~the~~ them ~~timing~~ or be able to reach or sustain profitability. We have never completed any late- stage clinical trials and may not be able to file ~~and~~ an ~~scope~~ IND application or other applications for regulatory approval to commence additional clinical trials on the timelines we expect. Even if we are able to complete such trials, the FDA or comparable foreign regulatory authorities may not permit us to proceed or could suspend or terminate any such trial after it has been initiated. We are early in our development efforts and will need to successfully complete later- stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market our product candidates. Carrying out clinical trials and the submission of a successful IND or CTA is a complicated process. We have not yet completed a Phase 1 / 2 clinical trial and have limited experience as a company in preparing, submitting and prosecuting regulatory filings. If topline results from our Phase 1 / 2 clinical trial of NGN- 401 are successful, we intend to engage with the FDA and other comparable foreign regulators to determine the requirements to support initiation of a pivotal clinical trial. If topline results from our Phase 1 / 2 clinical trial of NGN- 101 are successful, we intend to engage with the FDA and other comparable foreign regulators to determine if there is a streamlined pathway to approval for NGN- 101 for the treatment of CLN5 Batten disease. However, regulatory authorities may recommend changes to the study designs for NGN- 401 or NGN- 101, including the number and size of registrational clinical trials required to be conducted in such programs. In addition, regulatory authorities could require manufacturing changes or have us implement additional analytical processes prior to initiation of a future clinical trial. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of our product candidates. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in a regulatory meeting, such regulatory authorities may change their requirements in the future. The FDA or comparable foreign regulatory authorities may require the analysis of data from trials assessing different doses of the product candidate alone or in combination with other therapies to justify the selected dose prior to the initiation of large trials in a specific indication. Any delays or failure to initiate clinical trials or obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. We are subject to similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities. For our preclinical pipeline, if the IND- enabling studies support a decision to advance into clinical development, we would plan to submit an IND or CTA with a foreign regulatory authority. We may not be able

to file the IND or CTA in accordance with our desired timelines for future product candidates. For example, we may experience manufacturing delays or other delays with IND- enabling studies, including with suppliers, study sites, or third- party contractors and vendors on which we depend. Moreover, we cannot be sure that submission of an IND application will result in the FDA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that lead us to suspend or terminate such clinical trials. Risks Related to Manufacturing Gene therapies are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in the development or commercialization of our product candidates or otherwise harm our business. The manufacture of gene therapy products is technically complex and necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical studies. While we are currently establishing our own manufacturing facility to provide clinical and commercial supply of our product candidates, we expect to rely on contract manufacturers for certain portions of our manufacturing needs for the foreseeable future, such as those related to research grade material for our early preclinical studies. We have also relied on a third- party contract manufacturer to manufacture clinical supply for our Phase 1 / 2 clinical trial of NGN- 101. The manufacturers of biological and pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal regulations, as well as foreign requirements when applicable. Any failure of us or our CDMOs to adhere to or document compliance with such regulatory requirements could lead to a delay or interruption in the availability of our program materials for clinical trials or enforcement action from the FDA, EMA or other foreign regulatory authorities. If we or our manufacturers were to fail to comply with the FDA, EMA or other regulatory authority, it could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our potential future dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins and our ability to commercialize any product candidates that receive regulatory approval on a timely and competitive basis. Biological products are inherently difficult to manufacture. Although we believe that the manufacture of our product candidates may be simplified due to their shared raw materials and other similarities, we cannot be certain that this will be the case and we may be required to develop manufacturing methods that ultimately differ significantly between product candidates, which would require that we invest substantial time and capital to develop suitable manufacturing methods. Our program materials are manufactured using technically complex processes requiring specialized equipment and facilities, highly specific raw materials, cells, and reagents, and other production constraints. Our production process requires a number of highly specific raw materials, cells and reagents with limited suppliers. Even though we aim to have backup supplies of raw materials, cells and reagents whenever possible, we cannot be certain those supplies will be sufficient if our primary sources are unavailable. A shortage of a critical raw material, cell line, or reagent, or a technical issue during manufacturing, may lead to delays in clinical development or commercialization plans. We are particularly susceptible to any shortages, delays or inability to obtain suitable raw materials, given that all of our current and planned product candidates require this starting material. Any changes in the manufacturing of components of the raw materials we use could result in unanticipated or unfavorable effects in our manufacturing processes, resulting in delays. Once the biological products are manufactured, the product must be analyzed utilizing assays and meet pre- determined specifications in order to be used in certain preclinical studies, in any clinical trial, and, if approval is obtained, for commercial distribution. This testing is performed in- house and at third- party contract manufacturers. Delays or other unexpected obstacles in performing the tests and obtaining the results in- house or at a third- party contractor could result in unanticipated impact to our ability to supply material as needed for pre- clinical, clinical, or commercial needs. Neurogene and our contract manufacturers for AAV9 are subject to significant regulation with respect to manufacturing of our products. The third- party manufacturing facilities on which we rely, our in- house manufacturing facility, and any manufacturing facility that we may have in the future, may have limited capacity or fail to meet the applicable stringent regulatory requirements. We currently have relationships with a limited number of suppliers for the raw materials, including plasmids and virus banks, required by the manufacturing processes of our product candidates. Virus intended for use in our early preclinical studies has been and can be externally supplied; however, if we experience slowdowns or problems with our in- house manufacturing facility and are unable to establish or scale our internal manufacturing capabilities, we will need to continue to contract with manufacturers to produce the preclinical, clinical and commercial supply and such supply will be more uncertain and subject to delays. In addition, each supplier may require licenses to manufacture certain components of the supply if such processes are not owned by the supplier or in the public domain and we may be unable to license such intellectual property rights on reasonable commercial terms or to transfer or sublicense the intellectual property rights we may have with respect to such activities. All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for components of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including recordkeeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a biologics license application (“ BLA ”) or marketing authorization application (“ MAA ”) on a timely basis. Our facilities and quality

systems and the facilities and quality systems of some or all of our third- party contractors must pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our current or future product candidates. In addition, regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our current or future product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted, and they could put a hold on one or more of our clinical trials if the facilities of our CDMOs do not pass such audit or inspections. If these **facilities do not pass a pre- approval plant inspection, the FDA or other foreign regulatory agency approval of the** products **will not be granted. Regulatory authorities also may , at any time following approval of a product for sale, inspect or audit our manufacturing facilities or** ~~the~~ **those of our third- party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and / or time- consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business. If we or any of our third- party manufacturers fail to maintain regulatory compliance, the FDA or other foreign regulatory agencies can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre- existing approval. As a result, our business, financial condition and results of operations may be harmed. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA and / or MAA supplement, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully, if approved. Further, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose future potential revenue, if any. We depend on third- party suppliers for materials used in the manufacture of our product candidates, and the loss of these third- party suppliers or their inability to supply us with adequate materials could harm our business. We rely on third- party suppliers for certain materials and components required for the production of our product candidates. Our dependence on these third- party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing,** availability and **quality of supplies and delivery schedules. There is substantial demand and limited supply for certain of the raw materials used to manufacture gene therapy products. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our larger competitors. We cannot be certain that our suppliers will continue to provide us with the quantities of raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business. Delays in developing our manufacturing capabilities or failure to achieve operating efficiencies from such capabilities may require us to devote additional resources and management time to manufacturing operations and may delay our product development timelines. We have a GMP manufacturing facility located in Houston, Texas that includes process, analytical and bioanalytical development labs with experienced teams. NGN- 401 was manufactured at our Houston facility and clinical- grade product is available for dosing in the Phase 1 / 2 clinical trial of NGN- 401 that is currently enrolling patients. However, we will need to conduct additional NGN- 401 manufacturing campaigns to generate additional clinical supply, as well as supply for our preclinical studies for our discovery programs, and we may not be able to satisfy such supply through production at our own facility. Other risks relating to the manufacture of biologics and drug products include: production interruptions, delays in quality / release testing, equipment malfunctions, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities, war, cases of force majeure, acts of god (such as public health crises) or other events beyond our control and, in each case, could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. Any contamination or interruption in our manufacturing process, shortages of raw materials or failure of our suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules. Given the nature of gene therapy manufacturing, there is a risk of contamination. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects. We may not be able to successfully manufacture our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product**

candidates and commercializing resulting approved products, if any. To date, we have manufactured NGN- 401 in quantities and quality adequate for preclinical, toxicology and clinical studies. In order to conduct clinical trials for a product candidate and for commercialization of the resulting product if that product candidate is approved for sale, we will need to manufacture product candidates in additional cGMP campaigns or in larger batch sizes. We may not be able to successfully repeat or increase the manufacturing capacity for any of our product candidates in a timely or cost **- effective manner or at all. Significant changes or scale- up** of manufacturing **may require additional validation studies** , **which are costly and which regulatory authorities must review and approve. In addition, quality issues may arise during those changes or scale- up activities. If we are unable to successfully manufacture any of our product candidates in sufficient quality and quantity, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed or there may be a shortage in supply, which could significantly harm our business. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or approval from the FDA or foreign regulatory agencies. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of our future product candidates. Risks Related to Our Reliance on Third Parties Our discovery engine is supplemented by academic collaborations to expand our platform, which we rely upon to advance discovery and development of product candidates. For example, our collaboration with the University of Edinburgh is critical to our business. In December 2020, we entered into a Master Collaboration Agreement (the " MCA ") with the University of Edinburgh, which we rely on to conduct certain aspects of the preclinical development of our pipeline candidates, including NGN- 401 and all of our early- stage pipeline product candidates. Further, in March 2022, we entered into an exclusive license agreement with the University of Edinburgh for, with respect to certain University of Edinburgh- owned technology, a worldwide, exclusive, sublicensable license to develop, have developed, use, manufacture, have manufactured, supply, have supplied, sell, have sold, offer for sale, commercialize, import, export, register, reproduce, dispose of or otherwise exploit any products, processes, components, services and / or technologies incorporating the technology for the prevention or treatment of disease or medical or genetic conditions in humans. We also currently rely on the University of Edinburgh for portions of preclinical research capabilities under the direction of Dr. Stuart Cobb, Professor in Translational Neuroscience at the University of Edinburgh and our Chief Scientific Officer. Pursuant to the MCA, we and the University of Edinburgh agreed to collaborate on certain research and development projects (the " Projects "), and we agreed to provide funding for such Projects. In exchange for such funding, the University of Edinburgh grants us an option to exclusively license any intellectual property arising from such Projects. Either party has the right in certain circumstances to terminate the collaboration pursuant to the terms of the MCA. If the MCA is not renewed or is terminated, our pipeline of product candidates would be significantly adversely affected, and our business would be materially harmed. Following an amendment to the MCA in November 2023, the term of the research funding portion of the MCA, under which we have the ability to acquire exclusive rights to additional technology and gene therapy products, now expires in December 2026. If we need to extend the term of this provision beyond that date, we will need to negotiate an additional extension with the University of Edinburgh, and we may not be able to agree on such an extension on terms that are acceptable to us, or at all. We may have disagreements with the University of Edinburgh with respect to the interpretation of the MCA, use of resources or otherwise that could cause our relationship to deteriorate. As a result, the University of Edinburgh may reduce focus on, and resources allocated to, our programs, potentially delaying or terminating our ability to advance product candidates through preclinical studies. Additionally, if Dr. Cobb were to leave the University of Edinburgh or to otherwise no longer be meaningfully involved with us, our preclinical research and development capabilities may be substantially reduced. Further, under the MCA, the University of Edinburgh is primarily responsible for prosecuting and maintaining our licensed intellectual property, and it may fail to properly prosecute, maintain or defend such intellectual property. In such event, if we are unable to otherwise maintain or defend such intellectual property, we could face the potential invalidation of the intellectual property or be subjected to litigation or arbitration, any of which would be time- consuming and expensive. To enforce the licensed intellectual property rights under the MCA, we will need to coordinate with the University of Edinburgh, which could slow down or hamper our ability to enforce our licensed intellectual property rights. If this happens, we could face increased competition that could materially and adversely affect our business. For a further description of the MCA, see " Business — License Agreements. " Additionally, in May 2019, we entered into an exclusive license agreement with the University of North Carolina (" UNC ") for, with respect to the UNC invention known as " Optimized CLN5 Genes and Expression Cassettes and Their Use, " a worldwide, exclusive, sublicensable license to make, use, sell, have made, have sold, offer for sale and import any method or process, composition, product, or component part thereof for the prevention or treatment of disease or medical or genetic conditions, including CLN5 Batten disease or other diseases stemming from dysfunction of the CLN5 gene. We also currently have or may in the future engage in other academic collaborations to supplement our internal discovery and product development program. While these academic**

institutions have contractual obligations to us, they are independent entities and are not under our control or the control of our officers or directors. Our research and licensing agreements with academic collaborators generally provide academic collaborators with license maintenance fees, development and regulatory milestone payments, royalties on net sales of products and a portion of sublicense income that we receive. Upon the scheduled expiration of any academic collaboration, we may not be able to renew the related agreement, or any renewal could be on terms less favorable to us than those contained in the existing agreement. Furthermore, either we or the academic institution generally may terminate the sponsored research agreement for convenience following a specified notice period. If any of these academic institutions decides to not renew or to terminate the related agreement or decides to devote fewer resources to such activities, our discovery efforts would be diminished, while our royalty obligations, if any, would continue unmodified. We currently rely, and intend in the future to rely, on third parties to conduct a significant portion of our preclinical studies and existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials. We have engaged CROs or other third parties to conduct preclinical and IND enabling studies and our clinical trials, including our Phase 1 / 2 clinical trial of NGN- 401 and Phase 1 / 2 clinical trial of NGN- 101. We expect to continue to rely on third parties, including CROs, medical institutions and clinical investigators, to conduct those clinical trials. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business and financial condition. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not such third parties devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly. Further, while our reliance on these third parties for research and development activities will reduce our control over these activities, we will not be relieved of our responsibilities for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing **applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time** and **receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of NGN- 401 and NGN- 101 or any other product candidates. We currently store drug product for clinical trial sites in the United States, and currently rely on and expects in the future to rely on third parties to distribute product supplies for our clinical trials, as well as to store and distribute supply for clinical trial sites outside of the United States. Any performance failure on the part of Neurogene or our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential revenue. Risks Related to Our Business and Operations Over time, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical biological product development, technical operations, clinical operations, regulatory affairs, manufacturing and, potentially,** sales **, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial**

personnel and systems, expand our facilities and recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team working together in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our managerial, scientific and medical personnel, including our Founder and Chief Executive Officer, President and Chief Financial Officer, and Chief Scientific Officer, as well as other key members of our leadership team. Our executive officers may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or other employees. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time. Failure to attracting and retaining qualified personnel could materially and adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources on our employee recruitment and retention efforts. Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future growth may depend, in part, on our ability to develop and commercialize NGN- 401 or NGN- 101 or other product candidates in foreign markets for which we may rely on collaborations with third parties. We are not permitted to market or promote any product candidates before we receive regulatory approval from the applicable foreign regulatory authority, and may never receive such regulatory approval for any product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of NGN- 401 or NGN- 101 or other product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of NGN- 401 or NGN- 101 or other product candidates will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of NGN- 401 or NGN- 101 or other product candidates and ultimately commercialize such product candidates in foreign markets, we would be subject to the risks and uncertainties of operating in such foreign markets, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries. Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. It is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Our internal computer systems have suffered a security breach and in the future our systems, or those of any of our CROs, manufacturers, other contractors, third party service providers or consultants or potential future collaborators, may fail or suffer additional security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations. Despite the implementation of security measures in an effort to protect systems that store our information, given the size and complexity of such systems and the increasing amounts of information maintained on our internal information technology systems and those of our third- party CROs, other contractors (including sites performing our clinical trials), third- party service providers and supply chain companies, consultants and other partners, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and / or other third parties, or from cyber- attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. From time to time, we are subject to business email compromise attack attempts. In August 2023, we discovered a business email compromise attack that resulted in the misappropriation of approximately $ 0. 9 million. While we have implemented remedial measures in response to this incident, we cannot guarantee that such measures will prevent additional related, as well as unrelated incidents, or that we will be able to defend against or successfully remediate any such attacks that may occur in the future. If a material system failure, accident or security breach were to occur and cause interruptions in our operations or the operations of third- party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. Further,

since we sponsor clinical trials, any breach that compromises patient data and identities causing a breach of privacy could have significant adverse consequences on our business. For example, the loss of clinical trial data from completed or future clinical trials could affect trust in us, negatively impacting our ability to recruit for future clinical trials, result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or inappropriate disclosure of confidential proprietary information, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of NGN- 101 or NGN- 401 or other product candidates could be delayed. As our employees work remotely and use network connections, computers, and devices outside of our premises or network, including working at home, while in transit and in public locations, there are risks to our information technology systems and data. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders, patients or other individuals, regulators or, in certain circumstances, the media of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences, including damage to our reputation. We rely on third- party service providers and technologies to operate critical business systems, including to process sensitive information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences as a result. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our monetary, reputational and other damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been and will not be compromised. If we (or a third party upon whom we rely) experiences a security incident or is perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing personal information (including sensitive data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); increased investigation and compliance costs; financial loss; and other similar harms. Security incidents and attendant consequences may cause our stakeholders (including investors and potential customers) to stop supporting our business, deter new customers from our products, deter patients from participating in clinical trials and negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices or from disruptions in, or failure or security breach of, our systems or third- party systems where information important to our business operations or commercial development is stored, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation, injunctive restrictions on data processing and / or adverse publicity and could negatively affect our operating results and business. We, and third parties with whom we work, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which are changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, subject us to injunctive restrictions on data processing and otherwise cause a material adverse effect on our business, financial condition, and results of operations. See the sections entitled " Business — Government Regulation — Data Privacy and Security " and " — Other Regulatory Matters " for a more detailed description of the laws that may affect our ability to operate. 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 have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals

and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, 2023, Neurogene had net operating loss carryforwards for federal and state income tax purposes of $ 277. 9 million and $ 35. 1 million, respectively. The federal net operating losses will not be subject to expiration and can be carried forward indefinitely; however, they are limited to a deduction to 80 % of annual taxable income. The state net operating losses begin to expire in 2038. To the extent that our taxable income exceeds any current year operating losses, we plan to use our carryforwards to offset income that would otherwise be taxable. Also, for state income tax purposes, the extent to which states will conform to the federal laws is uncertain and there may be periods during which the use of net operating loss carryforwards are suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. In addition, under Section 382 of the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of more than 50 % (as measured by value) among a stockholder or one or more groups of stockholders who own at least 5 % of our stock within a three- year period. We have not performed an analysis to determine whether there has been an ownership change pursuant to Section 382. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Any such limitation, whether as the result of a public offering, private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years. We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or our stockholders. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States recently enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1 % excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act eliminates the currently available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years. The U. S. Congress is considering legislation that would restore the current deductibility of research and development expenditures, however, there is no assurance that the provision will be repealed or otherwise modified. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition. We may acquire businesses or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions. We may acquire additional businesses or products, 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 product candidates or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects. We maintain our cash at financial institutions, at times in balances that exceed federally- insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments. Our cash held in non- interest- bearing and interest- bearing accounts at financial institutions can at times exceed the Federal Deposit Insurance Corporation (“ FDIC ”) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders’ access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business. At the end of August 2023, we identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results, prevent fraud or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our share price. Our internal controls related to the cash disbursements process were not adequately designed to identify unauthorized payment requests, resulting in the identification of a material weakness. Specifically, at the end of August 2023, we discovered that we were subject to a business email compromise attack by a third party. This deficiency in our controls resulted in the diversion of payments

to fraudulent bank accounts. We determined that certain internal controls required for safeguarding our cash assets were not properly designed due to insufficient specificity regarding our policies and procedures surrounding supplier banking information changes, not identifying segregation of duties, and insufficient training on exercising professional skepticism. We therefore implemented steps to remediate this control deficiency, including increasing communication of and training around our controls relating to changes made to information, emphasizing security awareness and the importance of professional skepticism and designing a process to review supplier information changes prior to release of payments. While our management determined based on the assessment of internal control over financial reporting that as of December 31, 2023, this material weakness had been remediated, there can be no assurance that the remediation plans we implemented relating to this business email compromise attack will be successful in preventing a repeat of that attack or that we will be able to avoid potential future material weaknesses. If we are unable to successfully remediate existing or any future material weakness in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law and applicable stock exchange listing requirements regarding timely filing of periodic reports, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities. Risks Related to Intellectual Property Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage. We rely and expect to continue to rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from unfairly competing with us. Our success depends in large part on our ability to obtain and maintain patent protection for platform technologies, including our EXACT gene regulation platform, product candidates and their uses, as well as the ability to operate without infringing on or violating the proprietary rights of others. As of December 31, 2023, we license 17 patent applications, including U. S. patent applications, international patent applications under the Patent Cooperation Treaty or otherwise, and expect to continue to file patent applications in the United States and abroad related to discoveries and technologies that are important to our business. However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on product candidates worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions may be less extensive than those in the United States. As such, we do not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Competitors may operate in countries where we do not have patent protection and could then freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where patent protection has not been requested. Our intellectual property portfolio is at an early stage. As of December 31, 2023, we do not own or in- license any issued patents. Our pending and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Even if these patents are granted, they may be difficult to enforce. Further, any issued patents that may be licensed or owned covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the United States Patent and Trademark Office (" USPTO "). Further, if we encounter delays in any clinical trials or delays in obtaining regulatory approval, the period of time during which we could market product candidates under patent protection would be reduced. Thus, the patents that we may own or license may not afford any meaningful competitive advantage. In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share facilities or third- party consultants and vendors that we engage to perform researches, 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 the market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Lastly, if our trademarks and trade names are not registered or adequately protected, then we may not be able to build name recognition in markets of interest and our business may be adversely affected. We may not be successful in obtaining or maintaining necessary rights to product candidates through acquisitions and in- licenses. Because our development programs require and 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. 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 product candidates. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities **. In addition** , ~~price~~ **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 investment or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have** , ~~reimbursement coverage~~ **we may have to abandon development of the relevant product candidate** , **which could have a material adverse effect on our business, financial condition, results of operations, and prospects. While we will normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to a product candidate, there may be times when the filing and prosecution activities for patents** and patent ~~position. Competing~~ **applications relating to a** ~~products~~ **product** ~~could present superior treatment alternatives~~ **candidate are controlled by future licensors or collaboration partners. For example, we currently license several patent families from the University of Edinburgh covering the EXACT gene regulation platform, as well as the NGN- 401 product candidate and its uses. We also license a patent family covering the NGN- 101 product candidate and its uses from UNC. If any of such licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business** , including by ~~being~~ **payment of all applicable fees for patents covering a product candidate, we could lose rights to the intellectual property or exclusivity with respect to those rights, our ability to develop and commercialize such candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications which may be licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of licensees, future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution. Our future licensors may rely on third- party consultants or collaborators or on funds from third parties such that future licensors are not the sole and exclusive owners of the patents we in- license. If other third parties have ownership rights to future in- licensed patents, they may be able to license such patents to our competitors, and the competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing the same, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current technology or manufacturing methods, our product candidates, or future methods or product candidates, resulting in either an injunction prohibiting manufacture or future sales, or, with respect to future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation- related issues; whether and to what extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship and ownership of inventions and know- how resulting from the joint creations or use of intellectual property by future licensors and us and / or our partners; and the priority date of an invention of patented technology. Certain of our current product candidates and research programs are licensed from or based upon licenses from a third party and are field limited to certain indications. If these license agreements are terminated or interpreted to narrow our rights, our ability to advance our current product candidates or develop new product candidates based on these technologies will be materially adversely affected. We depend on, and will continue to depend on, our current licenses with UNC, the University of Edinburgh, Virovek, Inc. (“ Virovek ”) and Sigma- Aldrich Co. LLC (“ Sigma ”), and on licenses and sublicenses from other third parties, as well as potentially on other strategic relationships with third parties, for the research, development, manufacturing and commercialization of our current product candidates. If any of our licenses or relationships or any in- licenses on which our licenses are based are terminated or breached, we may: • lose our rights to develop and market our current product candidates; • lose patent or trade secret protection for our current product candidates; • experience significant delays in the development or commercialization of our current product candidates; • not be able to obtain any other licenses on acceptable terms, if at all; or • incur liability for damages. Additionally, even if not terminated or breached, our intellectual property licenses or sublicenses may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations. If we experience any of the foregoing, it could have a materially adverse effect on our business and could force us to cease operations. If we fail to comply with our obligations in any agreements under which we may license intellectual property rights from third**

parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We are party to license agreements with UNC, the University of Edinburgh, Virovek and Sigma and may from time to time in the future be party to other license and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. See " Business — License Agreements " for more **information regarding our license agreements with UNC, the University of Edinburgh, Virovek and Sigma. Despite our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements. If these licenses are terminated for any reason, or if the underlying patents fail to provide the intended exclusivity, we could lose significant rights and our ability to commercialize our current or future product candidates may be harmed, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse ~~effective~~ effect on our competitive position , ~~safer~~ business , ~~less~~ financial conditions, results of operations, and prospects. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to the development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations; • the priority of invention of any patented technology; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our current or future licensors and by us and our other partners. In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected current or future product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects. We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs, liability and diversion of resources, and prevent or delay us from commercializing potential products. Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate and guarantee that we can operate without infringing on or violating third party rights. If certain of our product candidates are ultimately granted regulatory approval, patent rights held by third parties, if found to be valid and enforceable, could be alleged to render one or more of such product candidates infringing. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon any affected product candidate and / or seek a license from the patent holder. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our business. Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be** expensive **and time- consuming. Any such claims could provoke these parties to assert counterclaims against us , including claims alleging that ~~or~~ our ~~marketed and~~ intellectual property, methods or products infringes their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks 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 such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy received may not be commercially valuable. Further, we may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to ~~sold~~ hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. If we are required to defend intellectual property actions brought by third parties, or if we sue to protect our own intellectual property rights**

or otherwise to protect our proprietary information and to prevent its disclosure, or if we are involved in other litigation, whether as a plaintiff or defendant, and whether or not successful, we may incur substantial legal expenses and the attention of our management and key personnel may be diverted from business operations. Further, some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than **we can because they have substantially greater resources. In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use, and may not be able to obtain such licenses on terms acceptable to us, if at all. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. We may be subject to claims that we have wrongfully hired an employee from a competitor or that employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. As is common in the biotechnology industry, in addition to employees, we engage consultants to assist in the development of our product candidates. Many of these consultants, and many of our employees, were or may have been previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees or consultants working on our behalf have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non- solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. We may litigate to defend ourselves against these claims, and even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, operations and financial condition. Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy- Smith America Invents Act (the " Leahy- Smith Act "), could increase the uncertainties and costs surrounding the prosecution of our owned and any future in- licensed patent applications and the maintenance, enforcement or defense of our owned and any future in-licensed issued patents. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost- effective avenues for competitors to challenge the validity of patents, and enable third- party submission of prior art to the USPTO during patent prosecution along with additional procedures to attack the validity of a patent at USPTO- administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 16, 2013, under the Leahy- Smith Act, the United States transitioned to a first- to- file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, our operations and prospects. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U. S. Supreme Court and U. S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. Accordingly, our competitive position may be impaired, and our business, financial condition, operations and prospects may be adversely affected. In addition, a European Unified Patent Court (" UPC ") came into force in June 2023. The UPC is a common patent court to hear patent infringement and revocation**

proceedings effective for member states of the European Union. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. We currently have three pending European applications, and if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents obtained. We may decide to opt out from the UPC for any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and / or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and / or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While 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 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. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our pending applications or any future issued patents, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Our current or future licensors may have relied on third- party consultants or collaborators or on funds from third parties, such as the U. S. government or academic institutions, such that our licensors are not the sole and exclusive owners of the patents we in- licensed. If other third parties have ownership rights or other rights to our in- licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, operations, and prospects. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20

years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and future licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Some intellectual property that we have in- licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non- U. S. manufacturers. Certain of the intellectual property rights we have licensed are generated through the use of U. S. government funding and are therefore subject to certain federal regulations. As a result, the U. S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh- Dole Act of 1980 (the " Bayh- Dole Act ") and implementing regulations. These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require our or our licensors' to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). The U. S. government also has the right to take title to these inventions if we fail, or the applicable licensor, fails to disclose the invention to the government and fails to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U. S. government requires that any products **embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. Risks Related to Government Regulation The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, such product candidates, and our ability to generate revenue will be materially impaired. The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our most advanced product candidates, NGN- 401 and NGN- 101, we must demonstrate through lengthy, complex and expensive preclinical and clinical trials that such product candidates are safe, pure and effective or potent for each targeted indication. Securing regulatory approval also requires the submission of information about the biological product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, a product candidate may not be effective or potent, may be only moderately effective or potent or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. A product candidate could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe, pure, and effective or potent for its proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected product- related side effects may be experienced by participants in our clinical trials or by individuals using drugs or biological products similar to a product candidate; we may be unable to demonstrate that a candidate' s clinical and other benefits outweigh its safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of a product candidate may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the**

formulation, labeling and / or the specifications of a product candidate; the FDA or comparable foreign regulatory authorities may 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 or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain regulatory approval to market NGN- 401 or NGN- 101 or other product candidates, which would significantly harm our business, results of operations and prospects. If we were to obtain approval, regulatory authorities may approve any such product candidate for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for a product candidate, we will not be able to commercialize, or will be delayed in commercializing, such product candidate and our ability to generate revenue may be materially impaired. Because gene therapy is novel and the regulatory landscape that governs any product candidates we may develop **is rigorous, complex, uncertain and subject to change, we cannot predict the time and cost of obtaining regulatory approval, if received at all, for any product candidates we may develop** . ~~Competitive~~ **The regulatory requirements that will govern any novel gene therapy product candidates we develop are not entirely clear and are subject to change. Within the broader genetic medicine field, very few therapeutic** products ~~may make~~ **have received marketing authorization from the FDA or the EMA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial overlap in those responsible for review and regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Therapeutic Products within its Center for Biologics Evaluation and Research (" CBER "), as part of its reorganization of the Office of Tissues and Advanced Therapies, to consolidate the review of gene therapy and related products. In addition, the Cellular, Tissue and Gene Therapies Advisory Committee advises CBER on its review. Our product candidates will need to meet safety, purity and efficacy or potency standards applicable to** any **new biologic under the regulatory framework administered by the FDA. In addition to FDA oversight and oversight by IRBs under guidelines promulgated by the National Institutes of Health (" NIH ") gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee (" IBC "), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. The same applies in the European Union. The EMA' s Committee for Advanced Therapies (" CAT ") is responsible for assessing the quality, safety, and efficacy of advanced- therapy medicinal** products **. Advanced- therapy medicinal products include gene therapy medicines, somatic- cell therapy medicines and tissue- engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a gene therapy product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that** we **comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any gene therapy product candidate we may** develop ~~obsolete~~ **, but that remains uncertain at this point. Adverse developments in preclinical studies or clinical trials conducted by others in the field of gene therapy and gene regulation products may cause the FDA, the EMA, and other regulatory authorities to revise the requirements** ~~or~~ **for** ~~noncompetitive before~~ **approval of any product candidates** we ~~recover~~ **may develop or limit the use of products utilizing gene regulation technologies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and** ~~the~~ **other regulatory authorities and the criteria these regulators use to determine the safety, purity and efficacy or potency of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as those being developed by us can be more** ~~expense~~ **expensive** ~~of~~ **and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are** developing **novel potential treatments for diseases in which, in some cases, there is little clinical experience with potential new endpoints** and ~~commercializing~~ **methodologies, heightened risk that the FDA, the EMA** ~~our~~ **or other regulatory authorities may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. In addition, we may not be able to identify or develop appropriate animal disease models to enable or support planned clinical development. Any natural history studies that we may conduct or rely upon in our clinical development may not be accepted by the FDA, EMA or other regulatory authorities. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of** ~~product~~ **products utilizing gene regulation technology in a timely manner or under**

technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval. The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates , or lead to significant post- approval limitations or restrictions . ~~Such competitors~~ As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could ~~also recruit~~ negatively impact our ~~employees~~ ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all. Disruptions at the FDA and other regulatory authorities could negatively affect the review of our regulatory submissions , which could negatively impact our ~~level~~ business. The ability of the FDA and other regulatory authorities to review and approve regulatory submissions can be affected by a variety of factors, including understaffing, disruptions caused by government shutdowns and public health crises. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates. In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control and manufacture our biological products safely and in accordance with regulatory requirements. This includes manufacturing the drug substance, developing an acceptable formulation, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, and demonstrating that our biological products meet stability requirements. Meeting these chemistry, manufacturing and control (" CMC ") requirements is a complex task that requires specialized expertise . If we are not able to meet the CMC requirements, we may not be successful in getting our products approved. We intend to deliver our product candidates via a drug delivery device that will have its own regulatory, development, supply and other risks. We intend to deliver our product candidates via a drug delivery device, such as a catheter ~~our~~ or ~~ability~~ other delivery system. There may be unforeseen technical complications related to ~~execute~~ the development activities required to bring such a product to market, including primary container compatibility and / or dose volume requirements. Our product candidates may not be approved or may be substantially delayed in receiving approval if the devices do not gain and / or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, some drug delivery devices are provided by single- source unaffiliated third- party companies. We may be dependent on the sustained cooperation and effort of those third- party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained, we may also be dependent on those third- party companies continuing to maintain such approvals or clearances once they have been received. Failure of third- party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications. We currently and may in the future conduct clinical trials for our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations. We plan to conduct clinical trials outside the United States, including in Australia, the UK, Europe or other foreign jurisdictions. For example, we currently intend to conduct our Phase 1 / 2 clinical trial for NGN- 401 in the United States and outside the United States. Our Phase 1 / 2 clinical trial for NGN- 101 is currently being conducted in the United States and in the UK. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan ~~. Any~~ , and which may result in our product candidates ~~we develop~~ not receiving approval or clearance for commercialization in the applicable jurisdiction. Even if the FDA accepts such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated. Other risks inherent in conducting international clinical trials include: foreign regulatory requirements, differences in healthcare services,

and differences in cultural customs that ~~are regulated~~ **could restrict or limit our ability to conduct our clinical trials; administrative burdens of conducting clinical trials under multiple sets of foreign regulations; foreign exchange fluctuations; diminished protection of intellectual property in some countries; and political and economic risks relevant to foreign countries. Our product candidates for which we intend to seek approval** as ~~biological products, or~~ biologics ~~,~~ may **face** ~~be subject to~~ competition sooner than anticipated. ~~Our product candidates may face~~ **The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, includes a subtitle called the Biologics Price** ~~competition~~ **Competition** ~~from other~~ **and Innovation Act of 2009 (" BPCIA "), which created an abbreviated approval pathway for biological** products that are ~~the same as or similar~~ **biosimilar** to ~~ours. For~~ **or interchangeable with** ~~any~~ **an** ~~product candidates that are~~ **FDA- licensed reference** biological ~~products~~ **product** ~~, if the FDA or comparable foreign regulatory authorities approve biosimilar versions of those product candidates, or such authorities do not grant our products appropriate periods of regulatory exclusivity, the sales of those products could be adversely impacted. The Biologics Price Competition and Innovation Act of 2009, or the BPCIA, was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar biological products (both highly similar and interchangeable biosimilar biological products). The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an approved biologic~~ . Under the BPCIA, an application for a **highly similar or "** biosimilar **"** product ~~cannot~~ **may not** be **submitted to the FDA until four years following the date that the reference product was first** approved **by the FDA. In addition, the approval of a biosimilar product may not be made effective** by the FDA until 12 years ~~after~~ **from** the **date on which the reference product was** first **approved** ~~licensure date of the reference product licensed under a BLA~~ . **During this** ~~The law is complex and some provisions are still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. A biological product submitted for licensure under a BLA is eligible for a period of exclusivity that commences on the date of its licensure, unless its date of licensure is not considered a date of first licensure because it falls within an exclusion under the PBCIA. Our biological product candidates may qualify for the BPCIA's~~ 12- year period of exclusivity, ~~but~~ **another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of its product. Our investigational biological products, if approved, could be considered reference products entitled to 12- year exclusivity. However,** there is a risk **that this exclusivity could be shortened due to congressional action or otherwise, or** that the FDA will not consider ~~our~~ **a** product ~~candidates~~ **candidate** to be reference products for competing products, potentially creating the opportunity for ~~biosimilar~~ competition sooner than anticipated. ~~There is~~ **Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have** also ~~a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. For example, there have~~ been ~~efforts to decrease this period of exclusivity to a shorter timeframe — future proposed budgets, international trade agreements, and other~~ -- **the subject** ~~arrangements or proposals may affect periods~~ of ~~exclusivity~~ **recent litigation** . **Moreover, the** ~~Most states have enacted substitution laws that permit substitution of only interchangeable biosimilars. The~~ extent to which a ~~highly similar~~ biosimilar, once approved, will be substituted for any ~~one of the~~ reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. **Even if we receive regulatory approval of NGN- 401 or NGN- 101 or other product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. Any regulatory approvals that we may receive for NGN- 401 or NGN- 101 or other product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety, purity and efficacy or potency of such product candidates, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy in order to approve a product candidate, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve a product candidate, the products and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, purity, efficacy or potency, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as on- going compliance with current cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.** If we ~~that~~ **abuse** ~~our~~ **or other** ~~internal operations and future business arrangements with third parties comply with applicable~~ healthcare laws and regulations ~~will involve substantial costs~~ .If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us,we may be subject to ~~significant~~ penalties,including **without limitation,significant** civil,criminal **,** and administrative penalties,damages,fines, **disgorgement,individual imprisonment,** exclusion from government ~~–~~funded healthcare programs, **such as Medicare and Medicaid,** integrity ~~oversight and reporting~~ obligations ~~to resolve allegations of non- compliance,disgorgement,individual imprisonment~~ ,contractual damages,reputational harm, **administrative burdens,** diminished profits **and future earnings,** and

the curtailment or restructuring of our operations. **If** ~~Further,defending against~~ any ~~such actions can~~ **physicians or other healthcare providers or entities with whom we expect to do business are found to not** be **in** ~~costly and time-~~ decide **which medications they will pay for and establish reimbursement levels. Government authorities and other third- party payors have attempted** to ~~pursue accelerated~~ **control costs by limiting coverage and the amount of reimbursement for particular medications. These entities may create preferential access policies for a competitor' s product, including a branded or generic / biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. Additionally, if any of our product candidates are approved and we are found to have improperly promoted off- label uses of those programs, we may become subject to significant liability, which would materially adversely affect our business and financial condition. See the sections entitled " Business — Government Regulation — Coverage and Reimbursement " and " — Regulation in the European Union " for a more detailed description of the government regulations and third- party payor practices that may affect our ability to commercialize product candidates. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell products outside the United States, to conduct clinical trials, and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Governments outside the United States may impose strict price controls, which may adversely affect our revenue, if any. In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing** approval for **a therapeutic. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators of ours may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of a product to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of** any ~~of~~ **product approved for marketing is unavailable** ~~our~~ **or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the UK determines which EU laws to replicate or replace. If the UK were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs. While we have received Fast Track designation for NGN- 401 for the treatment of Rett syndrome and for NGN- 101 for the treatment of CLN5 Batten disease and we may seek certain designations for our other** product candidates, ~~it~~ **including Breakthrough Therapy and Priority Review designations in the United States, we may not receive such designations, and even if we do, such designations** may not lead to a faster development or regulatory review or approval process **. We have received Fast Track designation in the United States for NGN- 401 for the treatment of Rett syndrome and for NGN- 101 for the treatment of CLN5 Batten disease, and we may seek additional designations for one or more of our other product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life- threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product' s application**

before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers a treatment for a serious condition, and if approved, would provide a significant improvement in safety or effectiveness where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review ~~and~~ an application is six months, rather than the standard review period of ten months. These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA, including the Fast Track designation we received for NGN- 401. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. The RMAT designation by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek ~~If we are unable to obtain approval under~~ an RMAT designation for our product candidates if the ~~accelerated pathway, we may be required to conduct additional~~ clinical data support such a designation ~~trials beyond those that we contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and / or delay the timing of obtaining, necessary marketing approvals. In the future, we may decide to pursue accelerated approval~~ for one or more ~~of our~~ product candidates. ~~Under~~ The RMAT designation program is intended to fulfill the requirement of the 21st Century Cures Act that the FDA ~~' s accelerated approval~~ facilitate an efficient development program ~~, the FDA may approve a drug or biological product~~ for , and expedite review of, any product that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life- threatening disease or condition ; and (3) preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides ~~a meaningful advantage over available therapies based upon~~ potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint ~~that is~~ reasonably likely to predict long- term clinical benefit, or may ~~on a clinical endpoint that can~~ be ~~measured earlier than irreversible morbidity~~ able to rely upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT designation does not change the standards ~~or~~ for ~~mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. For products~~ product ~~granted accelerated~~ approval, ~~post- marketing confirmatory trials are required to verify~~ and ~~describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence, and the FDA may require that the trial be designed, initiated, and / or fully enrolled prior to approval. If we were to pursue accelerated approval for a product candidate for a disease or condition, we would do so on the basis that~~ there is no ~~available therapy~~ assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for ~~that~~ eligibility cease to be met as clinical data emerges. We have received orphan drug designation for NGN- 401 for the treatment of Rett syndrome and for NGN- 101 for the treatment of CLN5 Batten disease , and we may seek orphan drug designation ~~or~~ for ~~condition. If standard of care were~~ certain future product candidates, but we may be unable to ~~evolve~~ obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause ~~or~~ our revenue, if any , to be reduced. We have received orphan drug designation from the FDA for NGN- 401 for the treatment of Rett syndrome and have also received orphan drug designation from the FDA and European Medicines Agency for NGN- 101 for the treatment of CLN5 Batten disease. Although we may seek orphan product designation for some ~~our~~ or ~~competitors were to~~ all of our other product candidates, we may never receive ~~full approval on~~ such designations. Under the ~~basis of a confirmatory trial for~~ Orphan Drug Act, the FDA may designate a drug or biological product ~~for~~ as an orphan drug if it is intended to treat a rare disease or condition ~~for which we are seeking accelerated approval before we receive accelerated approval~~ , defined ~~the disease or condition would no longer qualify~~ as ~~one~~ a patient population of fewer than 200, 000 in the United States, ~~for~~ or ~~which~~ a patient population greater than 200, 000 in the United States where there is no ~~available therapy~~ reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. In the European Union , the EMA' s Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life- threatening or chronically debilitating condition affecting not more than five in 10, 000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life- threatening, seriously debilitating or serious and ~~accelerated~~ chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. 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 application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity ~~our~~ or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval 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. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Even with an orphan drug designation for our current and potential future product candidates, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for an existing or future product candidate , that exclusivity may not effectively protect the product from competition because different drugs with different active moieties still can be approved for the same condition even with an orphan drug designation. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process. We have received Rare Pediatric Disease designation by the FDA for NGN- 401 for the treatment of Rett syndrome and for NGN- 101 for the treatment of CLN5 Batten disease. However, Rare Pediatric Disease designation for any of our product candidates does not guarantee that the BLA for the product will qualify for a priority review voucher upon approval, and it does not lead to a faster development or regulatory review process, or increase the likelihood that our product candidates will receive marketing approval. Under the Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying BLA for the treatment of a rare pediatric disease, the sponsor of such an application would be eligible for a rare pediatric disease priority review voucher that can be used to obtain priority review for a subsequent BLA or NDA. If a product candidate is designated before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026. While we have obtained Rare Pediatric Disease designations for NGN- 401 for the treatment of Rett syndrome and for NGN- 101 for the treatment of CLN5 Batten disease, it is unlikely that these product candidates will be approved by September 30, 2026. If approval is not obtained by then, we would not be in a position to obtain a priority review voucher, unless Congress further reauthorizes the program beyond the current sunset date in September 2024. Additionally, designation of a biological product for a rare pediatric disease does not guarantee that a BLA will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a Rare Pediatric Disease designation does not lead to faster development or regulatory review of the product or increase the likelihood that it will receive marketing approval. General Risk Factors Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, ~~occur~~ our business may not grow at similar rates, or at all . ~~Many cancer therapies rely~~ Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on ~~accelerated~~ assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties. Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, ~~and~~ the accepted price ~~treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials. Moreover, the FDA may withdraw approval of any product candidate approved under the accelerated approval pathway if,~~ for ~~example: • the trial~~ product, the ability to obtain coverage and reimbursement and whether we own the commercial rights ~~or~~ for ~~trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with such product; • other evidence demonstrates~~ that territory. If the number of our ~~product candidate~~ addressable patients is not ~~shown~~ as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. We may become exposed to ~~be safe~~ costly and damaging liability claims, either when testing a product candidate in the clinical or at the commercial stage, and ~~or~~ our ~~effective under~~ product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the ~~conditions of~~ research, development, manufacturing, marketing, and use ~~; •~~ of pharmaceutical products. While we ~~fail to conduct~~ currently have no products that have been approved for commercial sale, the current and future use of a product candidate in clinical trials, and the sale of any ~~required post~~ approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our products or any prospects for commercialization of our products. Although we believe we

currently maintain adequate product liability insurance for NGN - ~~approval trial of our~~ **401 and NGN- 101 and other** product ~~candidate~~ **candidates , it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Litigation costs and the outcome of litigation could have a material adverse effect on our business. From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, employment matters, security of patient and employee personal information, contractual relations** with **collaborators** ~~due diligence; or • we disseminate false or misleading promotional materials relating to the relevant product candidate. Recently, the accelerated approval pathway has come under scrutiny within the FDA~~ and **intellectual property rights. Litigation to defend ourselves against claims** by ~~Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, the Oncology Center of Excellence has recently announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post- marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies. Furthermore, in addition, Congress is considering various proposals to potentially make changes to the accelerated approval pathway, including proposals to increase the likelihood of withdrawal of approval in such circumstances. Risks Related to Our Reliance on Third Parties We rely on and expect to continue to rely on~~ third parties **, ~~to conduct certain of our~~ or** ~~preclinical studies and clinical trials. If those~~ **to enforce any rights that we may have against** third parties ~~do not perform as contractually required~~ , **may** ~~fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations, and prospects. We rely on third- party clinical investigators, CROs, clinical data management organizations, and consultants to assist or provide the design, conduct, supervision, and monitoring of preclinical studies and clinical trials of our product candidates, including certain third parties who will~~ continue to ~~assist in the wind- down of our NL- 201 Phase 1 clinical trial. To the extent we rely on these third parties, we will have less control over the timing, quality, and other aspects of certain preclinical studies and clinical trials than we would have had we conducted them on our own. Although we have agreements governing the activities of third parties, consultants are not and will not~~ be **necessary** ~~our employees, and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful, or timely in conducting our development work, preclinical studies or clinical trials~~ , which could result in ~~such work being delayed~~ **substantial costs and diversion of** ~~or~~ **our resources** ~~unsuccessful. If we cannot contract with acceptable third parties on commercially reasonable terms~~ , **causing** ~~or at all, or if these third parties do not carry out their contractual duties, satisfy applicable legal and regulatory requirements or meet expected deadlines, ourdevelopment programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The FDA generally requires preclinical studies to be conducted in accordance with Good Laboratory Practices, or GLPs, and clinical trials to be conducted in accordance with Good Clinical Practices, or GCPs, including for designing, conducting, recording, and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. If we or any of our third- party service providers fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional studies. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have~~ a material ~~and~~ adverse effect on our business, financial condition, results of operations ~~, and prospects. If any of our~~ - **or** ~~relationships with~~ **cash flows. Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as** ~~these~~ -- **the** ~~third~~ **COVID** - **19 pandemic** ~~party CROs or others terminate~~ , ~~we may not be able to enter into arrangements with alternative CROs~~ **political crises, geopolitical events, such as conflicts between Russia and Ukraine and between Israel and the surrounding regions,** or other ~~third parties or to do so~~ **macroeconomic conditions, which could have a material and adverse effect** on ~~commercially reasonable terms. Switching or~~ **our** ~~adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result~~ **results of operations and financial condition** ~~, delays may occur, which can materially impact our ability to meet our desired clinical development timelines~~ . **The global economy** ~~We do not own or operate facilities for drug manufacturing~~ , ~~storage~~ **including credit and financial markets** , **has experienced extreme volatility and** ~~distribution~~ --- **disruptions** , **including** ~~or quality testing. We therefore must rely on third- party contract manufacturers to manufacture bulk drug substances~~ , **among** ~~drug products, raw materials, samples, components, or~~ other **things** ~~materials and reports~~ , **diminished liquidity** and **credit** ~~conduct fill- finish services. Reliance on third- party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. Our third- party manufacturers may prioritize another customer' s needs in front of ours, especially in the event of a global pandemic. Additionally, raw materials and components used in the manufacturing process, particularly those for which we have~~

~~no other source or supplier, may not be available~~ **availability** ~~or may not be suitable or acceptable for use due to material or component defects~~ , **declines** ~~may be~~ in ~~short supply~~ **consumer confidence** , **declines** ~~and may significantly increase~~ in **economic growth** ~~price. There can be no assurance that our preclinical and clinical development product supplies will not be limited~~ , ~~or that they will be available at acceptable prices, if at all. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, global~~ supply chain **shortages** ~~disruption may hamper our ability to source materials needed for our research and development~~ , ~~including our preclinical trial programs, may increase~~ **increases** ~~our costs due to scarcity or may require us to buy materials on spec~~ in ~~advance of when we need it, which may impact our ability to budget or forecast expenditures, and may also hamper our ability to complete our preclinical trials on time, or at all. The manufacturing process for a product candidate is subject to review by the FDA, EMA, or other applicable regulatory authorities. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices, or cGMPs. Securing marketing approval also requires the submission of information~~ **inflation rates, higher interest rates, and uncertainty** about **economic** ~~the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or other applicable regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates and approval may be delayed. Moreover, although we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements, we are responsible for ensuring that our products comply with regulatory requirements. If any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do in a timely manner or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to repeat some of the development program. The costs and delays associated with the verification of a new manufacturer could negatively affect our ability~~ **stability** ~~to develop product candidates in a timely manner or within budget. We expect to continue to rely on third- party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA, EMA, or other applicable regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance, and corresponding maintenance of records and documents. If we are unable to obtain or maintain third- party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party' s failure to execute on our manufacturing requirements, comply with cGMPs, or maintain a compliance status acceptable to the FDA, EMA, or other applicable regulatory authorities could adversely affect our business in a number of ways, including: • an inability to initiate or continue clinical trials of product candidates under development; • delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates; • loss of the cooperation of future collaborators; • subjecting third- party manufacturing facilities to additional inspections by regulatory authorities; • requirements to cease distribution or to recall batches of our product candidates; and • in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products. Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments~~ . For example, ~~the global outbreak of~~ the COVID- 19 pandemic resulted in **widespread unemployment** ~~extended shutdowns of businesses in the United States~~ , ~~Canada,~~ **economic slowdown** and ~~many~~ **extreme volatility in** ~~other~~ -- **the capital markets** ~~countries andhad ripple effects to businesses around the world~~ . ~~Global health~~ **The Federal Reserve has raised interest rates multiple times in response to** concerns ~~, such as~~ **about inflation and it may not reduce interest rates in the near term or may raise** ~~the~~ **them** ~~COVID- 19 pandemic~~ **again. Higher interest rates** , **coupled with reduced government spending** and **volatility in** ~~the ensuing impacts on~~ financial markets **, may increase economic uncertainty** and **affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine, as well as the conflict between Israel and the surrounding regions, and rising tensions with China have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global** supply chain ~~logistics could also~~ **. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a** result **of economic or political uncertainty, political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain** in **a timely manner or on favorable terms, if at all. Increased inflation rates can** ~~adverse~~ **adversely** ~~effects~~ - **affect** ~~to~~ **us by increasing** our **costs** ~~manufacturing operations~~ , including **labor and employee benefit costs. We may in the future experience disruptions as a result of such macroeconomic conditions, including delays** ~~our~~ - **or** ~~ability to source raw materials and reagents. If our contract manufacturers were to encounter any of these~~ difficulties ~~,~~ **in initiating** ~~our~~ - **or expanding** ~~ability to provide our product candidates to patients in preclinical and~~ clinical trials ~~, or to provide product for treatment of patients once approved, would be jeopardized. Our third- party manufacturers may encounter difficulties in~~

~~production. If we or any of our third- party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our products for patients, if approved, could be delayed or stopped. Our product candidates are biopharmaceuticals,~~ and ~~the process of~~ manufacturing ~~biopharmaceuticals is complex, time- consuming, highly regulated, and subject to multiple risks. Our contract manufacturers must comply with legal requirements, cGMPs, and guidelines for the bulk manufacturing, fill- finish services, packaging, and storage of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our contract manufacturers may have limited experience in the manufacturing of cGMP batches. Manufacturing biopharmaceuticals is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered at our third- party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our third- party manufacturers' facilities are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny approval of our application until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. For example, certain resins used in the manufacture of biopharmaceuticals have recently experienced limited availability. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product, or provide fill- finish services, to specifications acceptable to the FDA, EMA, or other applicable regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch~~ of ~~the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials~~ **materials** ~~or~~**. Any one** ~~for~~ ~~-~~ **or** ~~commercialization, commercialization efforts~~ **a combination of these events** ~~would~~ **could** ~~be impaired, which would~~ have **a material** ~~an~~ **and** adverse effect on our ~~business,~~ **results of operations and** financial condition ~~,~~**. Risks Related to Owning Our Stock The market price of our common stock following the merger has been and may continue to be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include: • timing and** results of ~~operations,~~ **clinical trials** and **preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators; • failure to meet or exceed financial and development projections that we may provide to the public; • failure to meet or exceed the financial and development projections of the investment community; • failure to achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts; • announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors; • actions taken by regulatory agencies with** ~~prospects~~ ~~-~~ ~~-~~ **respect** ~~. Scaling up a biopharmaceutical~~ **to our product candidates, clinical studies,** manufacturing process ~~is a difficult and uncertain task, and our~~ ~~-~~ **or** ~~third~~ **sales and marketing terms; • disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; • additions or departures of key personnel; • significant lawsuits, including patent or stockholder litigation; • if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock; • changes in the market valuations of similar companies; • general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors; • sales of securities by us or our securityholders in the future; • if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates; • trading volume of our common stock; • announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments; • adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets; • the introduction of technological innovations or new therapies that compete with our products; and • period** ~~- party manufacturers may not~~ **to- period fluctuations in our financial results. Moreover, the stock markets in general** have ~~the necessary capabilities~~ **experienced substantial volatility that has often been unrelated** to ~~complete~~ the **operating performance of individual companies** ~~implementation, manufacturing, and development process . If we are unable to adequately validate~~ **These broad market fluctuations may also adversely affect the trading price of** ~~or~~ **our** ~~scale- up the manufacturing process at~~ **common stock. In addition, a recession, depression** ~~our~~ ~~-~~ **or** ~~current manufacturers~~ **other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company** ' ~~facilities~~ **s securities , stockholders have often instituted class action securities litigation against** ~~we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale- up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with~~ such ~~contract manufacturer an agreement for commercial supply and it~~ **companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe** is not **reflective of our intrinsic value** ~~certain we will be able to come to agreement on terms acceptable to us~~ **. Activist campaigns** ~~We cannot assure you~~ that **contest** ~~any stability or other issues relating to the manufacture of any of our~~ ~~-~~ **or** ~~product candidates~~ **conflict with** ~~or~~ **our strategic direction** ~~products will not occur in the future. Our de novo protein product candidates may not demonstrate sufficient long- term stability to support a BLA submission~~ or **seek** ~~obtain approval, or the product shelf life may be limited by stability results. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent~~ changes in the ~~properties~~ **composition of** ~~or~~ **our** ~~stability~~ **board** of **directors** ~~our product candidates that may not be detectable in final product testing. If~~

~~our third- party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse development affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write- offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and~~ could have an adverse effect on our **operating results** ~~business, prospects~~ , financial condition **and cash flows. On December 18** , **2023, we completed our business combination with Neurogene OpCo in accordance with the terms of the Agreement and Plan of Merger, dated as of July 17, 2023, by and among the Company, Project North Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, and Neurogene OpCo, pursuant to which, among other matters, Merger Sub merged with and into Neurogene OpCo, with Neurogene OpCo surviving as a wholly owned subsidiary of the Company (the " Reverse Merger "). In connection with the Reverse Merger, we declared a dividend, to each person who, as of immediately prior to the effective time of the Reverse Merger, was a stockholder of the Company or had the right to receive our common stock pursuant to** ~~and~~ **an** ~~results~~ **existing pre- funded warrant,** of **the right to receive one non- transferable contingent value right (each, a " CVR ") for each then outstanding share of our common stock (before giving effect to a 1- for- 4 reverse stock split (the " Reverse Stock Split ") that was implemented immediately prior to the effective time), each representing the non- transferable contractual right to receive certain contingent payments from the Company upon the occurrence of certain events within agreed time periods. Holders of** ~~operations~~ **options to purchase** ~~. As part of~~ our ~~process development efforts, we~~ **common stock outstanding immediately prior to the effective time of the merger will** also **received four CVRs** ~~may make changes to the manufacturing processes at various points during development,~~ for ~~various reasons,~~ **each share of our common stock that may be issued upon exercise of** such **option** ~~as controlling costs~~ , ~~achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such~~ **such** ~~changes carry the risk~~ that they will **receive** ~~not achieve their~~ **the** ~~intended objectives~~ **same number of CVRs as they would have received if the option had been exercised before the Reverse Stock Split** , **subject to certain conditions set forth in the CVR Agreement. Further, pursuant to the terms of the CVR Agreement, the holders of our common stock prior to the effective time of the Reverse Merger, including holders of existing pre- funded warrants** and **holders of options to purchase our common stock outstanding immediately prior to the effective time of the merger and exercised after the effective time of the merger, rather than all of our current holders of our common stock, are the primary recipients of** any **net** ~~of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process~~ **proceeds** ~~may require us~~ **of the disposition of the legacy assets related the business of Neoleukin Therapeutics, Inc. prior** to ~~perform ex vivo comparability studies and~~ **the effective time of the Reverse Merger, the mitigation of legacy lease obligations related the business of Neoleukin Therapeutics, Inc. prior** to ~~collect additional data~~ **the effective time of the Reverse Merger or receipt of any sales tax refund** from ~~patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. We may, in the future, seek to enter into collaborations with other third parties for the discovery, development, and commercialization of our product candidates. If our collaborators cease development efforts under our collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products, and we may never receive milestone payments or future royalties under these agreements. We expect a significant portion of our future revenue and cash resources to be derived from collaboration agreements or other similar agreements into which we may enter in the future for research, development, and commercialization of other therapeutic technologies or product candidates. Biopharmaceutical companies are our likely future collaborators for any marketing, distribution, development, licensing, or broader collaboration arrangements. If we fail to enter into future collaborations on commercially reasonable terms, or at all, or such collaborations are not successful, we may not be able to execute our strategy to develop certain targets, product candidates, or disease areas that we believe could benefit from the resources of either larger biopharmaceutical companies or those specialized in a particular area of relevance. Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development services, and resulting options to acquire any licenses of successful product candidates, and the achievement of milestones, contingent payments, and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our collaboration agreements will be substantially less than expected. With respect to future collaboration agreements, we expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them~~ **the State** ~~in these arrangements. Collaborations involving our product candidates may pose the following risks to us: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not pursue development and commercialization~~ of **Washington** ~~our product candidates or may elect not to continue or renew development or commercialization programs~~ based on ~~preclinical studies~~ **tax returns filed by the Company**

prior to the effective time of the Reverse Merger. Accordingly, we may be required to allocate a portion of ~~or~~ **our funds** ~~clinical trial results~~ , **time and resources to** ~~changes in the collaborators' strategic focus or available funding, or external factors~~ such ~~as~~ **activities** ~~an~~ **and not** ~~acquisition that diverts resources or~~ **our core** ~~creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program~~ **programs and the foregoing** ~~, stop a clinical trial, or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing; • collaborators~~ could ~~independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to~~ be **a distraction to** ~~successfully developed or can be commercialized under terms that are more economically attractive than ours~~ **our management** ~~; • collaborators with marketing~~ and **employees. As** ~~distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such~~ a ~~way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • disputes may arise between the collaborators and us that~~ result ~~in the delay or termination of the research~~ , ~~development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and • collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours~~ - **our operations** ~~were to be involved in a business combination, the continued pursuit~~ and ~~emphasis on our product development or commercialization program could be delayed, diminished, or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business,~~ financial condition ~~,~~ ~~results of operations, and prospects. Moreover, to the extent that any of our future collaborators were to terminate a collaboration agreement, we~~ may be ~~forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects. We may have conflicts with our collaborators that could delay or prevent the development or commercialization of our product candidates. We may have conflicts with our collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations, or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a collaborator to pay us milestone payments or royalties we believe are due to us under a collaboration, which could require us to raise additional capital; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement. We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could~~ adversely ~~affect~~ **affected** ~~our ability to develop and commercialize product candidates, impact our cash position, increase our expenses, and present significant distractions to our management. From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, and out- or in- licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time- consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. In addition, a significant number of recent business combinations among large pharmaceutical companies has resulted in a reduced number of potential future strategic partners. Our collaborators may consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA, or other applicable regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing, and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure~~

you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non- recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management' s time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition, or integration costs, write- downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty, and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership, and the inability to retain key employees of any acquired business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations, and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market. Risks Related to Our Business and Operations We may experience difficulties in preparing our operations for potential future growth, which could adversely affect our business. As of December 31, 2022, we had approximately 56 full- time employees, and in March 2023 announced a further corporate restructuring that reduced our headcount by approximately 70 % of the workforce in place at that time . We have **incurred,** also announced a shift to focusing on strategic alternatives for the Company and a suspension of our research **will continue to incur additional costs** and development programs in connection **increased demands upon management as a result of complying** with **the laws and regulations affecting public companies. We have incurred and will continue to incur significant legal, accounting and other expenses as a public company** that **may not be reflected** restructuring. If we are successful in completing **our historical financial statements, which reflect the operation of Neurogene as** a strategic transaction in **private company. Some of** the **these** future **additional expenses include costs associated with public company reporting obligations under the Securities Exchange Act of 1934** , we expect that we **as amended (the " Exchange Act "). Our management team consists of the executive officers of Neurogene prior to the merger. These executive officers and other personnel** will need to **devote substantial time to complying** invest in additional growth for the Company, which may include potentially expanding our development and regulatory capabilities, contracting with **public company** other organizations to provide manufacturing and other capabilities for us, and managing additional relationships with collaborators or partners, suppliers, and other organizations. Our ability to prepare for 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. Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan. We have experienced high turnover in the past year, and will rely on our remaining employees to execute any strategic alternatives the Board may approve under the current plan. The changes in our strategic direction and in our workforce may make retention of our current personnel both more important and more challenging. We cannot guarantee that we will be able to retain key employees necessary to carry out our revised strategic plan, and if such employees were to leave, we may not be able to identify and hire the personnel we need to replace them. Our success largely depends on the continued service of key management, advisors, and other specialized personnel. We currently do not maintain key person insurance on any of these individuals. The loss of one or more members of our management team or other key employees or advisors could delay any strategic initiative we may elect to pursue, and have a material and adverse effect on our business, financial condition, results of operations, and prospects. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty. If we are successful in completing a strategic transaction, we will need to retain the key managers, scientists and personnel necessary for the future growth of the Company following such transaction. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We also face competition for personnel from other companies, universities, public and private research institutions, government entities, and other organizations. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical, and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation, and commercialization. If we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can discover and develop product candidates will be limited which could have a material and adverse effect on our business, financial condition, results of operations, and prospects. Our relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third- party payors are and will be subject, directly and indirectly, to applicable anti- kickback, fraud and abuse, privacy, transparency, and other healthcare laws and regulations, which could expose us to penalties, including without limitation, civil, criminal, and administrative sanctions, civil penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, integrity obligations, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations. As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid, or other third- party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to

~~our future arrangements with third- party payors and customers who are in a position to purchase, recommend, and / or prescribe our product candidates for which we obtain marketing approval. These broadly applicable fraud and abuse and other healthcare laws and regulations may constrain our future business or financial arrangements and relationships with healthcare professionals, principal investigators, consultants, customers, and third- party payors and other entities, including our marketing practices, educational programs, and pricing policies. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to, the following: • the federal Anti- Kickback Statute, which, among other things, prohibits persons from knowingly and willfully soliciting, offering, receiving, providing, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; • federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, and, among other things, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent, or from knowingly making a false statement to improperly avoid, decrease, or conceal an obligation to pay money to the federal government; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items, or services relating to healthcare matters; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as health plans, healthcare clearinghouses, and healthcare providers; • the federal Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program (with certain exceptions) to report annually to CMS information related to " payments or other transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), physician assistants, certain types of advance practice nurses, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other " transfers of value " to such physician owners and their immediate family members; and • analogous local, state, and foreign laws and regulations, including: state anti- kickback and false claims laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by state governmental and non- governmental third- party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; local, state, and foreign laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities and file reports relating to pricing and marketing information and / or register their pharmaceutical sales representatives; and local, state, and foreign laws that govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre- empted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our internal operations and any business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Recent healthcare reform legislation has also strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement~~ **requirements** ~~of the federal Anti- Kickback Statute, such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud~~ and abuse or other healthcare laws and regulations..... business are found to not be in compliance with applicable laws ~~, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Moreover, we expect there will continue to be federal, state, local and foreign laws~~ and regulations **to ensure** ~~, proposed and implemented, that could impact our operations and business~~ **we comply with all of these requirements** . ~~The extent~~ **Any changes we make** to ~~which future legislation~~ **comply with these obligations may not be sufficient to allow us to satisfy** ~~or~~ **our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and** regulations, **coupled** ~~if any, relating to healthcare fraud abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain. We may form strategic alliances in the future, and we may not realize the benefits of such alliances. We may form strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements~~ with ~~third parties that we believe will complement or augment our existing business. These relationships or those like them~~ - **the** ~~may require us to incur non- recurring and other charges,~~ increase ~~our near- and long- term expenditures, issue securities that dilute our stockholders, or disrupt our management and business. In addition, we face significant competition~~ in ~~seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our~~

efforts to establish a strategic partnership or other alternative arrangements for any future drug candidates and programs because our research and development pipeline may be insufficient, our drug candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our drug candidates and programs as having the requisite potential **litigation exposure associated** to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with **being a public** our existing operations and company culture. We cannot be certain that , following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our drug candidates could also delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market. Our employees, independent contractors, principal investigators, CROs, consultants, vendors, and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, CROs, consultants, vendors, and collaboration partners, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state data privacy and security, fraud and abuse and other healthcare laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Specifically, 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 may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct for our directors, officers, and employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, results of operations, financial condition, and cash flows from future prospects, including the imposition of significant fines or other sanctions. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We will face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercialize any of our product candidates. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant time and costs to defend the related litigation; • substantial monetary awards to trial participants or patients; • loss of revenue; and • the inability to commercialize any product candidates that we may develop. We currently maintain product liability insurance coverage for our clinical trials, but the amount may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage for each new clinical trial we begin and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We may engage in future acquisitions that could disrupt our business, cause dilution to our stockholders, and harm our business, results of operations, financial condition, and cash flows and future prospects. We may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our future product candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may: • issue stock that would dilute our stockholders' percentage of ownership; • incur debt and assume liabilities; and • incur amortization expenses related to intangible assets or incur large and immediate write- offs. We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets, or investors. Furthermore, future acquisitions could pose numerous additional risks to our operations, including: • problems integrating the purchased business, products, or technologies; • increases to our expenses; • the failure to discover undisclosed liabilities of the acquired asset or company; • diversion of management' s attention from their day- to- day responsibilities; • harm to our operating results or financial condition; • entrance into markets in which we have limited or no prior experience; and • potential loss of key employees, particularly those of the acquired entity. We may not be able to complete any acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition. Our ability to use our U. S. net operating losses to offset future taxable income will be subject to Section 382 limitations and may be limited by other factors. As of December 31, 2022, we had U. S. net operating losses, or NOLs, of $ 124. 9 million, for federal tax purposes, for which we have recorded a full valuation allowance, and R & D credit carryovers of $ 3. 9 million, which may be offset by future taxable income. The R & D credit carryforwards and certain of our NOL carryforwards will expire in various years beginning in 2028 if not used. Unused losses incurred in taxable years beginning on or prior to December 31, 2017 will carry forward to offset future taxable income, if any, until such unused losses expire. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, unused U. S. federal NOLs generated in tax years beginning after December 31, 2017, will not

expire and may be carried forward indefinitely, but the deductibility of such federal NOLs (particularly those generated in taxable years beginning after December 31, 2020) is limited to 80 % of current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. Furthermore, use of certain of our NOLs and R & D credit carryforwards will be subject to annual limitations on their use as a result of ownership changes under the rules of Sections 382 and 383 of the Internal Revenue Code, or the Code that have historically occurred. Based on our Section 382 analysis to date, we underwent ownership changes in August 2015 and August 2019. As a result of these ownership changes, we believe that certain of our NOLs will be likely to expire before they are able to be used under Section 382. In addition, we may experience ownership changes in the future as a result of future changes in our stock ownership, some of which changes are outside of our control, and as a result, our ability to utilize NOL and R & D credit carryforwards could become further limited under Sections 382 and 383, and the tax benefits related to our NOLs and R & D credits may be diminished or lost. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition, cash flow and future prospects. As a result, even if we attain profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows. Risks Related to Intellectual Property Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in- licenses of intellectual property rights of others, for our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. Under our License Agreement with the University of Washington, dated July 8, 2019, as amended on October 29, 2020, effective July 24, 2020, and again on December 27, 2021, effective December 15, 2021, we have an exclusive license to develop and commercialize products covered by patent applications with claims covering the composition of matter of certain molecule families as well as methods of using the computational algorithms that form the basis of the Neoleukin design process. However, we may not be able to apply for patents on certain aspects of our product candidates or methods in a timely fashion or at all. Further, we may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce, and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing, and prosecution of all patent applications that we license from third parties, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Patents we currently hold, or in the future may obtain, may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our future issued or granted patents will not later be found to be invalid or unenforceable or that any future issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions. The U. S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a large number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The process of obtaining patents is time consuming, expensive and sometimes unpredictable. Once granted, for a given period after allowance or grant patents may remain open to opposition, interference, re- examination, post-grant review, inter partes review, nullification, or derivation action in court or before patent offices or similar proceedings, during which time third parties can raise objections against such initial grant. Such proceedings may continue for a protracted period of time and an adverse determination in any such proceedings could reduce the scope of the allowed or granted claims thus attacked, or could result in our patents being invalidated in whole or in part, or being held unenforceable, which could allow third parties to commercialize our product candidates and compete directly with us without payment to us. In addition, there can be no assurance that: • others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license; • we or our licensors, or our future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license; • we or our licensors, or our future collaborators are the first to file patent applications covering certain aspects of our inventions; • others will not independently develop similar or alternative technologies or

duplicate any of our technologies without infringing our intellectual property rights; • a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed; • any issued patents that we own or have licensed or that we may license in the future will provide us with any competitive advantages, or will not be challenged by third parties; • we may develop additional proprietary technologies that are patentable; • the patents of others will not have a material or adverse effect on our business, financial condition, results of operations, and prospects; and • our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets. If we or our licensors or collaborators fail to maintain patent applications and later- issued patents covering our product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations, and prospects. In addition, if the breadth or strength of protection provided by our patent applications and later- issued patents is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. We could be required to incur significant expenses to strengthen our intellectual property rights, and our intellectual property rights may be inadequate to protect our competitive position. The patent prosecution process is expensive and time- consuming, and we or our future potential licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future potential licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. 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. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Our patent applications and the enforcement or defense of our issued patents may be impacted by the application of or changes in U. S. and foreign standards. The standards that the USPTO and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our product candidates. Similarly, the standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the validation enforceability, or term of our patent. For example, the U. S. Supreme Court has recently modified some legal standards applied by the USPTO in examination of U. S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license. In addition, changes to the U. S. patent system have come into force under the Leahy- Smith America Invents Act, or the Leahy- Smith Act, which was signed into law in September 2011. The Leahy- Smith Act included a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy- Smith Act, the United States transitioned in March 2013 to a " first to file " system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in opposition, derivation, reexamination, inter- partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position. While we cannot predict with certainty the impact the Leahy- Smith Act or any potential future changes to the U. S. or foreign patent systems will have on the operation of our business, the Leahy- Smith Act and such future changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects. Obtaining and maintaining any patent protection we may receive will depend on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural,

documentary, fee payment and other similar provisions during the patent application process. While 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 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. If we or our future licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected. We may be subject to claims by third parties claiming ownership of what we regard as our own intellectual property, which may prevent, delay or otherwise interfere with our product discovery and development efforts. Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non- disclosure and non- competition agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. In addition, third parties may from time to time make claims over what we regard as our intellectual property, or we may get into disputes with licensors or licensees of our intellectual property rights over the interpretation of the license terms. If a third party claims that we infringe, misappropriate or otherwise violate their intellectual property rights, we may face a number of issues, including, but not limited to: • infringement and other intellectual property claims that, regardless of merit, may be expensive and time- consuming to litigate and may divert our management' s attention from our core business; • substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner' s attorneys' fees; • a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third- party licenses its product rights or proprietary technology to us, which it is not required to do, on commercially reasonable terms or at all; • if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and / or grant cross- licenses to intellectual property rights for our product candidates; • the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time; and • there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Our licensors may have the right to terminate their license agreements with us or pursue damages or other legal remedies. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful and could result in a finding that such patents are unenforceable or invalid. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may 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. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Conversely, we may choose to challenge the patentability of claims in a third party' s U. S. patent by requesting that the USPTO review the patent claims in re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings), or we may choose to challenge a third party' s patent in patent opposition proceedings in the Canadian Intellectual Property Office, or CIPO, the European Patent Office, or EPO, or another foreign patent office. Even if successful, 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, CIPO, 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 product candidates or proprietary technologies.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. Any of the foregoing 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 products, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturing organizations, consultants, advisors and other third parties. We also generally enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know- how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not currently clear how the FDA' s disclosure policies may change in the future, if at all. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our product candidates throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or future collaborators may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so 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, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Intellectual property rights do not necessarily provide sufficient protection of our technology or address all potential threats to any competitive advantage we may have. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: • Others may be able to make compounds that are the same as or similar to our future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed. • We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed. • We or any of our licensors or strategic partners might not have

been the first to file patent applications covering certain of our inventions. • Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights. • It is possible that our pending patent applications will not lead to issued patents. • It is possible that there are prior public disclosures that could invalidate our owned or exclusively licensed patents, as the case may be, or parts of our owned or exclusively licensed patents. • It is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours. • It is possible that our owned or exclusively licensed patents or patent applications omit one or more individuals that should be listed as inventors or include one or more individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or such omitted individuals may grant licenses to third parties. • Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors. • Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as 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 have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents. • We may not develop additional proprietary technologies that are patentable. • The patents of others may have an adverse effect on our business. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and exclusive licenses. The growth of our business may depend in part on our ability to acquire, license or use third- party proprietary rights. For example, our product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing pre- existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patents we may co- own with third parties, we may require licenses to such co- owners interest to such patents. 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 we identify as necessary or important in our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be nonexclusive, which means our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. We sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer. Some intellectual property that we have in- licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- U. S. manufacturers. Inventions contained within some of our in- licensed patents and patent applications may have been made using U. S. government funding or other non- governmental funding. As a result, the U. S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh- Dole Act of 1980, or Bayh- Dole Act, and implementing regulations. We rely on our licensors to ensure compliance with applicable obligations arising from such funding, such as timely reporting, an obligation associated with in- licensed patents and patent applications. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents. For example, the government could have certain rights in such in- licensed patents, including a non- exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non- commercial purposes. In addition, our rights in such in- licensed government- funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly. Risks Related to Ownership of Our Common Stock Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance, resulting in substantial losses for investors. The trading price of our common stock has been, and is likely to continue to be, volatile for the foreseeable future. The trading price of our common stock could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "

~~Risk Factors ” section and elsewhere in this report, these factors include: • the success of competitive products or technologies; • regulatory actions with respect to our products or our competitors’ products; • actual or anticipated changes in our growth rate relative to our competitors; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; • results of clinical trials, including both safety and efficacy, of any of our current or future product candidates or those of our competitors; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any of our future product candidates or clinical development programs; • the results of our efforts to in- license or acquire additional product candidates or products; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be similar to us; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; • announcement or expectation of additional financing efforts; • sales of our common stock by us, our insiders or our other stockholders; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; and • general economic, industry and market conditions, such as market volatility and economic uncertainty due to rising interest rates, inflation, the war in Ukraine, and the COVID- 19 pandemic. In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks or any of a broad range of other risks, including those described in this “ Risk Factors ” section and elsewhere in this report, could have a dramatic and material adverse impact on the market price of our common stock. Some provisions of our charter documents and Delaware law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation, or certificate of incorporation, and amended and restated bylaws, or bylaws, as well as provisions of Delaware law, could~~ make it more difficult for **us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors’ and officers’ insurance, on acceptable terms. Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. We expect to still qualify as a “ smaller reporting company, ” as such term is defined in Rule 12b- 2 under the Exchange Act, in at least the near term, which allows us to take advantage of many exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Once we are no longer a smaller reporting company or otherwise no longer qualify for this exemption, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant additional legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, any of which would require additional financial and management resources. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of Nasdaq. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in each Annual Report on Form 10- K, as required by Section 404 of the Sarbanes- Oxley Act. Prior to the merger in December 2023, the operating and finance teams of Neurogene were part of a private company, and therefore were not previously required to test internal controls within a specified period. As a result, we have incurred and may continue to incur substantial professional fees and internal costs to expand our accounting and finance functions as well as to expend significant management efforts. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’ s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. For example, our internal controls related to the cash disbursements process were not adequately designed to identify unauthorized payment requests, resulting in the identification of a material weakness. Specifically, at the end of August 2023, we discovered that we were subject to a business email compromise attack by** a third party ~~to acquire us~~ **. This deficiency in ~~or~~ our ~~increase~~ controls resulted in the diversion of payments to a fraudulent bank account. While**

management has determined in its assessment of our internal control over financial reporting as of December 31, 2023, that we have remediated this material weakness, ~~the~~ **there** ~~cost of acquiring us~~ **can be no assurance that the remediation will prevent similar attacks in the future or that we will not identify other material weaknesses in the future. If we are unable to successfully remediate a material weakness in our internal control over financial reporting** , ~~even~~ **or** if ~~doing so~~ **we identify any other material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also** ~~would~~ **could** ~~benefit~~ **become subject to investigations by Nasdaq, the SEC or other regulatory authorities. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Our certificate of incorporation and bylaws, as well as provisions under Delaware law, could make an acquisition of the company more difficult and may prevent attempts by** our stockholders ~~,~~ **to replace** or remove ~~our current~~ management. ~~These include provisions~~ **Provisions** ~~that: • permit~~ **in our certificate of incorporation and bylaws may discourage, delay** ~~our~~ **or prevent a merger** ~~board of directors to issue up to 5~~ , ~~000, 000 shares~~ **acquisition or other change in control** of ~~preferred stock, with any rights, preferences and privileges as they~~ **the company** ~~may designate; • provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; • require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent; • provide~~ that stockholders ~~seeking to present proposals before a meeting of~~ **may consider favorable, including transactions in which our common** stockholders ~~or to nominate candidates~~ **might otherwise receive a premium price** for **their shares. These provisions could** ~~election as directors at a meeting of stockholders must provide advance notice in writing, and~~ also **limit** ~~specify requirements as to~~ the **price that investors might be willing to pay in the future** ~~form and content of a stockholder' s notice; • not provide~~ for ~~cumulative voting rights, thereby allowing the holders of a majority of the~~ shares of **our** common stock ~~entitled to vote in any election~~ **, thereby depressing the market price of our common stock. In addition, because our board** of directors **will be responsible** ~~to elect all of the directors standing~~ for **appointing** ~~election; and • provide that special meetings of our stockholders may be called only by~~ the ~~board~~ **members** of ~~directors or~~ **our management team,** ~~by such person or persons requested by a majority of the board of directors to call such meetings. These~~ **these** provisions may frustrate or prevent any attempts by our stockholders to replace or remove ~~our~~ current management by making it more difficult for stockholders to replace members of our board of directors **. Among other things** , **these provisions: • establish a classified board of directors such that all members of the board are not elected at one time; • allow the authorized number of our directors to be changed only by resolution of our board of directors; • limit the manner in which stockholders can remove directors from the board; • establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings; • require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; • limit** who ~~are responsible~~ **may call a special meeting of stockholders; • authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and • require the approval of the holders of at least 66 2 / 3 % of the votes that all stockholders would be entitled to cast to amend** ~~for~~ **or** ~~appointing the members~~ **repeal certain provisions** of **our charter** ~~our~~ **or** ~~management~~ **bylaws** . **Moreover,** ~~Because~~ **because** we are incorporated in Delaware, we are governed by the provisions of Section 203 of the **DGCL** ~~Delaware General Corporation Law~~ , which ~~may discourage, delay~~ **prohibits stockholders owning in excess of 15 % of** ~~or~~ **our** ~~prevent someone~~ **outstanding voting stock** from ~~acquiring us or~~ merging **or combining** with us ~~whether~~ **. Although we believe these provisions collectively will provide** ~~or~~ **for** ~~not it is desired~~ **an opportunity to receive higher bids** by **requiring potential acquirors to negotiate with** ~~or~~ **our board of directors, they would apply even if the offer may be considered** beneficial ~~to our~~ **by some** stockholders. ~~Under Delaware law~~ **Our governing documents provide that** , ~~a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock~~ unless **we consent in writing to** the ~~holder has held~~ **selection of an alternative forum, certain designated courts will be** the ~~stock~~ **sole and exclusive forum** for ~~three years~~ **certain legal actions between us and** ~~or~~ **our stockholders** , **which** ~~among other things, the board of directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control~~ could limit ~~the opportunity for~~ our stockholders **'** ~~to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock. The exclusive forum provisions in our certificate of incorporation and bylaws may limit a stockholder' s~~ ability to ~~bring~~ **obtain** a **favorable** ~~claim in a~~ judicial forum ~~that it finds favorable~~ for disputes with us or ~~any of~~ our directors, officers, ~~or other~~ employees **or agents** ~~, which may discourage lawsuits with respect to such claims~~ . Our **governing documents** ~~certificate of incorporation, to the fullest extent permitted by law, provides~~ **provide** that **, unless we consent in writing to an alternative forum,** the Court of Chancery of the State of Delaware **is** ~~will be~~ the **sole and** exclusive forum for ~~:~~ **state law claims for (i)** any derivative action or proceeding brought on ~~our~~ **the company' s** behalf ~~;~~ **, (ii)** any action asserting a **claim of or based on a** breach of **a** fiduciary duty ~~;~~ **owed by any of our current or former directors, officers, or other employees to the company or our stockholders, (iii)** any action asserting a claim ~~against us~~ arising pursuant to **any provision of** ~~the Delaware General Corporation Law, or~~ the DGCL, ~~our~~ **the** certificate of incorporation ~~, or our~~ **or the** bylaws ~~;~~ **, (iv) any action to interpret, apply, enforce** or **determine the validity of the certificate of incorporation or bylaws, or (v)** any action asserting a claim ~~against us~~ that is governed by the

internal affairs doctrine . This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934 , **in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named** as amended **defendants therein** , **which** or **for purposes** the Exchange Act. It could apply, however, to a suit that falls within one or more of **this risk factor refers to herein** the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act of 1933, as amended, or the **" Delaware Forum** Securities Act, inasmuch as Section 22 of the Securities Act, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision **Provision** with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder . **" Our governing documents further** In April 2020, we amended and restated our bylaws to provide that **, unless we consent in writing to an alternative forum,** 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, **which** or **for a purposes of this risk factor refers to herein as the "** Federal Forum Provision. Our decision to adopt a **" Neither the Delaware Forum Provision nor the** Federal Forum Provision followed a decision by **will apply to any causes of action arising under** the Supreme **Exchange Act. In addition, any person or entity purchasing or otherwise acquiring any interest in shares of** Court -- **our capital stock will be deemed to have notice** of **and consented to** the **foregoing** State of Delaware **Forum** holding that such provisions - **Provision and** 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 **; provided** should be enforced in a particular case , application of **however, that stockholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. The Delaware Forum Provision and** the Federal Forum Provision means that suits brought by **may impose additional litigation costs on** our stockholders to enforce **in pursuing** any **such claims, particularly if such stockholders do not reside** duty or liability created by the Securities Act must be brought in **or near the** federal court and cannot be brought in state **State** court **of Delaware** . **Additionally,** These **these** choice of forum provisions **selection clauses** may limit a **our** stockholder **stockholders '** ' s ability to bring a claim in a judicial forum that **it they** finds - **find** favorable for disputes with us or any of our directors, officers , or other employees, which may discourage **such** lawsuits **against us and** with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in ourcertificate of incorporation or **our** bylaws to be inapplicable or unenforceable in **directors, officers and employees even though** an action, **if successful** we may incur additional costs associated with resolving such action in other jurisdictions , which could harm **might benefit our stockholders. If our existing stockholders sell,** our - **or indicate** business, results of operations and financial condition. We are no longer an **intention** " emerging growth company, " however, we are still a " smaller reporting company, " and the reduced disclosure requirements applicable to smaller reporting companies may make **sell, substantial amounts of** our common stock less attractive to investors. Although we ceased to be an " emerging growth company, " as defined in the **public** Jumpstart Our Business Startups Act of 2012, or JOBS Act, on December 31, 2019, we are a " smaller reporting company, " meaning that the market value of our stock held by non- affiliates is less than $ 700. 0 million and our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non- affiliates is less than $ 250. 0 million or (ii) our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and the market value of our stock held by non- affiliates is less than $ 700. 0 million. As a smaller reporting company , we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We cannot predict if investors will find our common stock less attractive because we may rely on these -- **the** exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may become a" large accelerated filer" and have to comply with more rigorous disclosure and reporting requirements and regulations. If we cease to be a " smaller reporting company " or a " non- accelerated filer " in the future, we may be subject to certain disclosure requirements that are applicable to other public companies that had not been applicable to us previously. These requirements include: • compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting once we are an accelerated filer or large accelerated filer; • compliance with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; and • full disclosure and analysis obligations regarding executive compensation. There can be no assurance that we will be able to comply with the applicable regulations in a timely manner, if at all. Inability to comply with these regulations could impact our ability to raise additional capital. General Risk Factors We may be subject to securities litigation, which is expensive and could divert management attention. The trading price of our common stock has been and will continue to 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. Our principal stockholders, directors and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates together beneficially own a majority of our outstanding voting stock. These stockholders are able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders are able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage

unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our business, results of operations, financial condition and cash flows and future prospects, which may adversely affect investor confidence in us and, as a result, the value of our common stock. The Sarbanes- Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures and that we furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes- Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we are not an accelerated filer or large accelerated filer, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we fail to identify and to remediate any significant deficiencies or material weaknesses that may be identified, or encounter problems or delays in the implementation of internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline . **Based on shares outstanding as of December 31 , 2023** and we could be subject to sanctions or investigations by the Nasdaq Stock Market , or Nasdaq, the SEC or other **there approximately 16** regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting , **887, 026 shares of** or **our common stock outstanding or issuable on exercise of prefunded warrants** to implement **purchase common stock. Of these shares, approximately 3, 637, 374 shares outstanding or issuable upon exercise of prefunded warrants or vested options to purchase common stock will be available** or **for** maintain **sale in** other -- **the** effective control systems required of public companies, could also restrict our future access to the capital markets **market beginning June 15, 2024, which** . Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is **180 days after** accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. Our internal computer and information systems, or those -- **the closing of** used by our CROs, or other -- **the** contractors or consultants **merger on December 18** , **2023** may fail or suffer security incidents (**the " Closing "** e. g., cyber- attacks) or other technical failures , which could **as a** result in a material disruption of our development programs and may result in extensive and costly legal compliance requirements. Our de novo protein technology depends on sophisticated computational facilities and storage of vast amounts of data which could be lost or stolen. In the ordinary course of our business, we collect, store, and transmit confidential information, including intellectual property, proprietary business information and personal information. Despite the implementation of appropriate security measures, our internal computer and information systems and those -- **the expiration** of **lock** our current and any future CROs, and other contractors or consultants may become vulnerable to damage from security incidents (such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or information technology incidents caused by threat actors, technological vulnerabilities or human error), natural disasters, terrorism, war, including the recent conflict between Russia and Ukraine, and telecommunication and electrical failures. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to

result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be significantly delayed. Our internal and outsourced information technology systems and infrastructure are also vulnerable to damage from natural disasters, terrorism, war, including Russia' s recent invasion of Ukraine, telecommunication and electrical failures. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud- based systems during the COVID- 19 pandemic, could compromise our ability to perform our day- to- day operations, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition. Although we devote resources to protect our information systems, we realize that cyberattacks resulting in a security incident are a threat, and there can be no assurance of our efforts will prevent information security breaches that would result in business, legal, financial, or reputational harm to the Company, or would have a material adverse effect on our results of operations and financial condition. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. The COVID- 19 pandemic is generally increasing the attack surface available to criminals, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. Federal, state, and foreign government requirements include obligations of companies to notify regulators and / or individuals of security breaches involving personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow- up actions related **agreements between us and certain of our securityholders. All other outstanding shares of common stock and any shares issuable on exercise of prefunded warrants or vested options** to a security breach **purchase our common stock, other than shares held by our affiliates or otherwise subject to restrictions on vesting and exercise, are freely tradable, without restriction, in the public market. If these shares are sold, the trading price of our common stock** could impact our reputation **decline. Our executive officers, directors** and cause us to incur **principal stockholders beneficially own a** significant **percentage of** costs. Any failure to prevent or **our outstanding common stock. As a** mitigate security breaches or improper access to, use, disclosure or other misappropriation of our data or consumers' personal data could result in significant legal liability , **if** such as under state breach notification laws, federal law (including HIPAA / HITECH), and international law (e. g., GDPR). Compliance with these and any **stockholders were to choose to act** other **together** applicable privacy and data security laws and regulations is a rigorous and time- intensive process , and we may be required to put in place additional mechanisms ensuring compliance with the **they** new data protection rules and possible government oversight. Our failure to comply with such laws or to adequately secure the information we hold could **would** result in **be able to control or** significant **significantly** liability **influence all matters submitted to** or **our stockholders** reputational harm and, in turn, a material adverse effect on our client base, member base and revenue. Further, if we are unable to generate or maintain access to essential patient samples or data for **approval** our research and development and manufacturing activities for our programs, our business could be materially adversely affected. Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses. Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics such as the COVID- 19 pandemic and other natural or manmade disasters or business interruptions, for which we are predominantly self- insured. We do not carry insurance for all categories of risk that our business may encounter. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third- party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure of being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster. In addition, the long- term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters. Further, any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, results of operations, financial condition and cash flows from future prospects. In addition, 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. Likewise, the capital and credit markets may be adversely affected by the recent conflict between Russia and Ukraine, and the possibility of a wider European or global conflict, and global sanctions imposed in response thereto. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the 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, or cause our customers to delay making payments for our services. Further, the conflict in Ukraine could increase incidences of cybersecurity attacks against companies in the United States as retaliation for sanctions levied against Russia, which could increase our risk of being the subject of such an attack. We cannot anticipate all of the ways in which the foregoing, and the current economic climate, financial market conditions and geopolitical developments 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. We have incurred and will incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives. As a public company, we have incurred and will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses will likely

~~increase even more given we are no longer an " emerging growth company. " We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Protection Act~~ , as well as **our** ~~rules adopted, and to be adopted, by the SEC and Nasdaq. Our~~ management and **affairs** ~~other personnel devote a substantial amount of time to these compliance initiatives~~ . ~~Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and made some activities more time- consuming and costly. The increased costs will increase our net loss. We cannot predict or~~ **For example** ~~estimate the amount or timing of additional costs we may incur to respond to these requirements. 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. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market could occur at any 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. We have in the past and may in the future grant rights to some of our stockholders that require us to register the resale of our common stock or other securities on behalf of~~ these stockholders ~~and / or facilitate public offerings of~~ **, if they choose to act together, would control** ~~our~~ **or significantly influence** ~~securities held by these~~ -- **the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of Neurogene on terms that other** stockholders **may desire. We may be exposed to increased litigation** , including **stockholder** ~~in connection with potential future acquisition or capital- raising transactions. For example, in connection with our public offering of common stock on September 19, 2016, we entered into a registration rights agreement with the Baker Entities that together, based on information available to us, collectively beneficially owned approximately 45. 1 % of our common stock as of September 19, 2016. Under the registration rights agreement, we agree that, if at any time and from time to time after December 19, 2016, the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act, we would be obligated to effect such registration. On January 6, 2017, pursuant to the registration rights agreement, we registered for resale, from time to time, up to 10, 536, 092 shares of our common stock held by the Baker Entities. Our registration obligations under this registration rights agreement cover all shares now held or hereafter acquired by the Baker Entities, would be in effect for up to ten years, and would include our obligation~~ -- **litigation** ~~to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future. If the Baker Entities or any other holders of registration rights with respect to our common stock~~ , ~~by exercising their registration and / or underwriting rights or otherwise, sell a large number of our shares, or the market perceives that the Baker Entities or such holders intend to sell a large number of our shares, this could adversely affect the market price of our common stock. We have registered all currently reserved shares of common stock that we may issue under our equity compensation plans and intend to register in the future any additional reserved or issued shares of common stock. These registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We have also filed a shelf registration statement covering the sale of up to $ 400. 0 million of any combination of our common stock, preferred stock, debt securities, or warrants and may conduct one or more sales of securities pursuant to such registration statement, from time to time. In November 2021, we entered into an ATM " at- the- market " Equity Offering Sales Agreement, or Sales Agreement, with BofA Securities, Inc., or BofA, pursuant to which, from time to time, we may offer and sell through BofA up to $ 40. 0 million of the common stock registered under the shelf registration statement pursuant to one or more " at the market " offerings. Sales of our common stock under the Sales Agreement with BofA 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. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock- related securities, including the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our stockholders. New investors could also gain rights, preferences, and privileges senior to those of holders of our common stock. Pursuant to our 2014 Equity Incentive Plan, as amended, or 2014 Plan, our compensation committee is authorized to grant equity- based incentive awards to our directors, executive officers, and other employees and service providers, including officers, employees and service providers of our subsidiaries and affiliates. Future option grants and issuances of common stock under our 2014 Plan may~~ have an adverse effect on **our business and operations. We may be exposed to increased litigation from stockholders, suppliers and other third parties, which may have an adverse impact on our business and results of operations or may cause disruptions to our operations. In the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in** the market ~~price~~ **prices** of ~~our common~~ **these companies'** stock **, and we may also be subject to threats of litigation based on our recent merger activity. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations** . If **equity research** ~~securities or industry~~ analysts do not publish research or **reports, or** publish ~~inaccurate or~~ unfavorable research **or reports,** about **us,** our business **or our market** , our stock price and trading volume could decline. The trading market for our common stock ~~depends in part on~~ **will be influenced by** the research and reports that **equity research** ~~securities or industry~~ analysts publish about us **and** ~~, or~~ our business **. Equity research analysts may elect to not provide research coverage of our common stock, and such lack of research coverage**

may adversely affect the market price of our common stock. If we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research . If one or more **equity research** ~~of the securities or industry~~ analysts ~~who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease~~ **ceases** coverage of **Neurogene** ~~our~~ **or** ~~company or fail~~ **fails** to publish reports on us regularly, demand for our **common** stock could decrease, which ~~might~~ **in turn could** cause our stock price ~~and~~ **or** trading volume to decline. **The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or our stockholders. We continue to assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations or employees to determine the potential effect on our business and any assumptions we make about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For example, the United States recently enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1 % excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years. The U. S. Congress is considering legislation that would restore the current deductibility of research and development expenditures; however, there is no assurance that the current provision will be repealed or otherwise modified. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business condition.**