Risk Factors Comparison 2024-02-27 to 2023-03-16 Form: 10-K

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

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report and in other documents that we file with the ~~Securities and Exchange Commission, or~~ SEC ~~,~~ in evaluating the Company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impact our business, prospects, financial condition and results of operations. Item 1A. Risk Factors. In evaluating the Company and our business, careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report and in other documents that we file with the SEC. Our business faces significant risks and uncertainties. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties were to actually occur, our business, prospects, financial condition or results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any one factor or combination of factors may have on our business, prospects, financial condition or results of operations. Risks related to our financial position and need for additional capital We ~~are early in our development efforts,~~ have a limited operating history, have not completed any **later- stage** clinical trials, have no products approved for commercial sale and have not generated any revenue, which may make it difficult for investors to evaluate our current business and likelihood of success and viability. We are a biopharmaceutical company with a limited operating history upon which investors can evaluate our business and prospects. We were incorporated in January 2017 and commenced significant operations in 2018, have never completed ~~any~~ **a Phase 2 or Phase 3** clinical ~~trials~~ **trial** , have no products approved for commercial sale and have never generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have devoted substantially all of our resources to research and development activities, including with respect to NVL- 520, our ROS1- selective inhibitor, NVL- 655, our ALK- selective inhibitor, NVL- 330, our HER2- selective inhibitor, and our discovery programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully complete ~~any~~ **Phase 2 or Phase 3** clinical trials, obtain marketing 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. As a result, it may be more difficult for investors to evaluate our likelihood of success and viability than it could be if we had a longer operating history. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by ~~early- stage~~ biopharmaceutical companies **at our stage of development** in rapidly evolving fields. We also expect that, as we advance our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer. We have incurred significant net losses in each period since our inception, and we expect to continue to incur significant net losses for the foreseeable future. We have incurred significant net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through private placements and public offerings of securities. Our net losses were $ **126. 2 million and $** 81. 9 ~~million and $ 46. 3~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~160~~ **286** . ~~1~~ **3** million. We ~~are still in the early stages of development of our product candidates and~~ have not yet completed any **Phase 2 or Phase 3** clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products. We expect to continue to incur significant and increasing expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the pace of our development activities and the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve our objectives relating to the discovery, development and commercialization of our product candidates. We rely on our team' s expertise in chemistry, structure- based drug design, oncology drug development, business development and our patient- driven approach to develop our product candidates. Our business depends significantly on the success of our approach and the development and commercialization of the product candidates that we discover with this approach. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives, including: • successful and timely completion of preclinical and clinical development of NVL- 520, NVL- 655, NVL- 330 and any future product

candidates from our discovery programs, and any other future programs; • maintaining current and establishing new relationships with CROs and clinical sites for the clinical development of NVL- 520, NVL- 655, NVL- 330 and any future product candidates from our current or future discovery programs; • timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development; • developing an efficient and scalable manufacturing process for our product candidates, including the production of finished products that are appropriately packaged for sale if our product candidates obtain marketing approvals; • maintaining current and establishing new commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved; • successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in- house or with one or more collaborators; • maintaining an acceptable safety profile following any marketing approval of our product candidates; • commercial acceptance of our product candidates by patients, the medical community and third- party payors, including the willingness of physicians to use our product candidates, if approved, in lieu of (or ~~as a second- line, third- line or later treatment~~ in conjunction with) other approved therapies; • satisfying any required post-marketing approval commitments to applicable regulatory authorities; • identifying, assessing and developing new product candidates; • obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the U. S. and internationally; • defending against third- party interference or infringement claims, if any; • entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates; • obtaining coverage and adequate reimbursement by third- party payors for our product candidates, if approved; • addressing any competing therapies and technological and market developments; and • attracting, hiring and retaining qualified personnel. We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations. We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs, future commercialization efforts, product development or other operations. Since our inception, we have used substantial amounts of cash to fund our operations, and our expenses will increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, our product candidates. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time- consuming, expensive and uncertain process that takes years to complete. Even if one or more of our product candidates or any future product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other regulatory authorities to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our clinical trials, including our planned and anticipated clinical trials, are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of our product candidates or any future product candidates that we develop. We have initiated Phase 1 / 2 clinical trials for our parallel lead programs, NVL-520 and NVL- 655. We have not yet **initiated** ~~received clearance to begin~~ clinical trials for any of our other product candidates, including NVL- 330, and we are not permitted to market or promote any product candidate before we receive marketing approval from the FDA, EMA or any comparable foreign regulatory authorities. We also continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of the date of this Annual Report, will be sufficient to fund our operating expenses and capital expenditure requirements into ~~the second half of 2025~~ **2027** . Advancing the development of NVL- 520, NVL- 655, NVL- 330 and our discovery programs will require a significant amount of capital. Our existing cash, cash equivalents and marketable securities will not be sufficient to fund ~~any~~ **all** of our product candidates through regulatory approval, and we anticipate needing to raise additional capital to complete the development and commercialization of our product candidates. Our estimate as to how long we expect our existing cash, cash equivalents and marketable securities to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. We will be required to obtain further funding through public or private equity financings, debt financings, collaborative agreements, licensing arrangements or other sources of financing, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Our ability to raise additional funds may be adversely impacted by general economic conditions, both inside and outside the U. S., including disruptions to, and instability and volatility in, the credit and financial markets in the U. S. and worldwide, including heightened inflation, interest rate and currency rate fluctuations, and economic slowdown or recession as well as concerns related to ~~the COVID- 19 pandemic and~~ **public health emergencies, natural disasters or** geopolitical events, including civil or political unrest **or** ~~(such as the ongoing~~ military ~~conflict~~ **conflicts** ~~between Ukraine and Russia)~~ . In addition, market instability and volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. To the extent that we raise additional capital through the sale of equity or convertible debt securities, each investor' s ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect each

investor' s rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research or drug development programs, clinical trials or future commercialization efforts. Risks related to the discovery, development and commercialization of our product candidates **Our** ~~We are early in our development efforts and our~~ future prospects are substantially dependent on NVL- 520, NVL- 655 and NVL- 330. If we are unable to advance these product candidates through development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed. We ~~are early in our development efforts. We~~ have initiated Phase 1 / 2 clinical trials for NVL- 520 and NVL- 655. All of our other product candidates, including NVL- 330, are still in preclinical development and have never been tested in humans. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful preclinical and clinical development and eventual commercialization of one or more product candidates. We are not permitted to market or promote any product candidate before we receive marketing approval from the FDA, EMA or any comparable foreign regulatory authorities, and we may never receive such marketing approvals. The success of **our product candidates** ~~NVL- 520, NVL- 655 and NVL- 330~~ will depend on several factors, including the following: • successful and timely completion of preclinical studies; • submission of INDs in the U. S. and CTAs and / or comparable applications outside the U. S. for regulatory authority review and agreement to proceed with our clinical trials; • ~~our ability to address any potential delays resulting from factors related to the COVID- 19 pandemic and other global geopolitical events; •~~ successful initiation and completion of clinical trials; • successful and timely patient selection and enrollment in and completion of clinical trials; • maintaining and establishing relationships with CROs and clinical sites for the clinical development of our product candidates both in the U. S. and internationally; • maintaining and growing an organization of chemists, medical ~~professionals~~ and clinical development professionals **and others** who can develop and commercialize our product candidates; • the frequency and severity of adverse events in clinical trials; • obtaining positive data that support demonstration of efficacy, safety and tolerability profiles and durability of effect for our product candidates that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval; • the timely receipt of marketing approvals from applicable regulatory authorities; • the timely identification, development and approval of companion diagnostic tests, if required; • the extent of any required post- marketing approval commitments to applicable regulatory authorities; • the maintenance of existing or the establishment of new supply arrangements with third- party drug product suppliers and manufacturers for clinical development and, if approved, commercialization of our product candidates; • obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the U. S. and internationally; • the protection of our rights in our intellectual property portfolio; • establishing sales, marketing and distribution capabilities and the successful launch of commercial sales of our product candidates if and when approved for marketing, whether alone or in collaboration with others; • maintaining an acceptable safety profile following any marketing approval; • commercial acceptance by patients, the medical community and third- party payors, including the willingness of physicians to use our product candidates, if approved, in lieu of (or ~~as a second- line treatment~~ in conjunction with) other approved therapies; ~~and~~ • our ability to compete with other therapies **; and • our ability to address any potential delays resulting from factors related to public health emergencies, natural disasters or geopolitical events** . We do not have complete control over many of these factors, including certain aspects of preclinical and 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. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates from our lead programs, which would materially harm our business. If we do not receive marketing approvals for such product candidates, we may not be able to continue our operations. Our preclinical studies and clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization. Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and the ultimate outcome is uncertain. Failure can occur at any time during the preclinical study and clinical trial processes ~~, and, because our product candidates are in an early stage of development~~ , there is a high risk of failure, and we may never succeed in developing marketable products. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including: • failure of our product candidates in preclinical studies or clinical trials to demonstrate safety and efficacy; • receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials; • negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain research, discovery and / or drug development programs; • the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated, particularly if there are other trials enrolling the same or overlapping precisely targeted patient populations, or participants dropping out of these clinical trials at a higher rate than anticipated; • third- party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • the suspension or termination of our clinical trials for various reasons, including non- compliance with regulatory requirements or a finding that our product candidates have undesirable adverse events or other

unexpected characteristics or risks; • the cost of clinical trials of our product candidates being greater than anticipated; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and • regulators revising the requirements for approving our product candidates. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we are currently contemplating, if we are unable to successfully complete clinical trials of our product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be delayed in seeking and obtaining marketing approval, if we receive such approval at all, receive more limited or restrictive marketing approval, be subject to additional post- marketing testing requirements or have the drug removed from the market after obtaining marketing approval. Our discovery and development activities are focused on the development of targeted therapeutics for patients with cancer- associated genomic alterations, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs may never lead to approved or marketable products. The discovery and development of targeted therapeutics for patients with cancer- associated genomic alterations is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are evolving. 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 **and clinical trials to date** , that the genomic alterations targeted by our programs are oncogenic drivers, clinical results may not confirm this hypothesis or may only confirm it for certain alterations or certain tumor types. The patient populations for our product candidates are limited to those with specific target alterations and may not be completely defined but are substantially smaller than the general treated cancer population, and we will need to screen and identify these patients with targeted alterations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific alterations respond to our product candidates and the ability to identify such alterations, which may require the use of companion diagnostic tests. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval for each mutation type and commercialize our product candidates and achieve profitability. We do not know if our approach of focusing on treating patients with cancer- associated genomic alterations will be successful, and if our approach is unsuccessful, our business will suffer. Any delays in the commencement or completion, or termination or suspension, of our planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before we can initiate clinical trials of a product candidate in any indication, we must submit the results of preclinical studies to the FDA, EMA or other comparable foreign regulatory authorities along with other information, including information about the product candidate' s chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission under which we must receive authorization to proceed with clinical development. The FDA, EMA or other comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before they allow us to initiate clinical trials under any IND, CTA or comparable application which may lead to additional delays and increase the costs of our preclinical development programs. Before obtaining marketing approval from the FDA of NVL- 520, NVL- 655 or NVL- 330 or of any other future product candidate in any indication, we must conduct extensive clinical studies to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by our CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase. We have initiated Phase 1 / 2 clinical trials for NVL- 520 and NVL- 655 **, and plan to initiate a Phase 1 clinical trial for NVL- 330 in 2024** . IND submission must become effective prior to initiating any clinical trials in the U. S. for ~~NVL- 330 or~~ any of our future product candidates. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRB or IEC of the institutions in which such trials are being conducted, by a DSMB for such trial or by the FDA or foreign regulatory authorities. Such authorities may impose such a suspension or termination 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 or foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse events, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs / IECs for reexamination, which may impact the costs, timing or successful completion of a clinical trial **. Further, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of the FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other " pivotal study " of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late- stage clinical trials of FDA- regulated products. Similarly, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate CTA to be submitted in each member state, to both the competent national health authority and an IEC, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member**

state, leading to a single decision per member state . Certain of our current or future scientific advisors or consultants who receive compensation from us may become investigators for our future clinical trials. Under certain circumstances, we may be required to report some of these relationships to the FDA. Although we expect any such relationships to be within the FDA' s guidelines, 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 study. 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 our product candidates. If we experience delays in the completion of, or termination of, any clinical trial of any product candidate, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenue, which may harm our business, financial condition, results of operations and prospects significantly. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities. We will be required to demonstrate with substantial evidence through well- controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and ~~, because our product candidates are in an early stage of development,~~ there is a high risk of failure and we may never succeed in developing marketable products. The results of preclinical studies may not be predictive of the results of clinical trials of our product candidates, and the results of early clinical trials may not be predictive of the results of later- stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. Favorable results from certain animal studies may not accurately predict the results of other animal studies or of human trials, due to the inherent biologic differences in species, the differences between testing conditions in animal studies and human trials, and the particular goals, purposes, and designs of the relevant studies and trials. We have, for example, observed preclinical CNS activity of NVL- ~~655 and NVL-~~ 330 in studies with rats and mice. These studies may or may not be predictive of CNS penetrance and activity of ~~NVL- 655 or~~ NVL- 330 in human trials. Similarly, certain of our hypotheses regarding the potential clinical and therapeutic benefits of our product candidates compared to other products or molecules in development are based on observations from our preclinical studies, and results from such preclinical studies are not necessarily predictive of the results of later preclinical studies or clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller- scale clinical trials may not be predictive of eventual safety or effectiveness in large- scale pivotal clinical trials. 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 drugs. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as products. The development of our product candidates and our stock price may also be impacted by inferences, whether correct or not, that are drawn between the success or failure of preclinical studies or clinical trials of our competitors or other companies in the biopharmaceutical industry, in addition to our own preclinical studies and clinical trials. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. Any preclinical studies or clinical trials that we conduct may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. We do not know whether any clinical trials we ~~may~~ conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates. In addition to NVL- 520, NVL- 655 and NVL- 330, our prospects depend in part upon discovering, developing and commercializing additional product candidates from our discovery programs, which may fail in development or suffer delays that adversely affect their commercial viability. Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize NVL- 520, NVL- 655, NVL- 330 and future product candidates from our discovery programs. A research candidate can unexpectedly fail at any stage of development. The historical failure rate for research candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate. The success of other research candidates **that** we may develop will depend on many factors, including the following: •

generating sufficient data to support the initiation or continuation of preclinical studies and clinical trials; **• obtaining regulatory permission to initiate clinical trials; • contracting with the necessary parties to conduct clinical trials; • successful enrollment of patients in, and the completion of, clinical trials on a timely basis; • the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; • adverse events in clinical trials; and** • addressing any delays resulting from factors related to **public health emergencies, natural disasters or** ~~the ongoing COVID- 19 pandemic and other global~~ geopolitical events ~~; • obtaining regulatory permission to initiate clinical trials; • contracting with the necessary parties to conduct clinical trials; • successful enrollment of patients in, and the completion of, clinical trials on a timely basis; • the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and • adverse events in clinical trials~~ . Even if we successfully advance any research candidates into preclinical and clinical development, their success will be subject to all of the preclinical, clinical, regulatory and commercial risks described elsewhere in this " Risk Factors " section. Accordingly, there can be no assurance that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from any product candidates. Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our approach to build a pipeline of product candidates with commercial value. A key element of our strategy, which is unproven, is to use and expand our expertise in chemistry, structure- based drug design and patient- driven approach to build a pipeline of product candidates and progress these product candidates through clinical development. Although our research and development efforts to date have resulted in the discovery of and initiation of clinical development of NVL- 520 and NVL- 655, and preclinical development of NVL- 330, such product candidates ~~,~~ and any other product candidates we may develop may not be safe or effective as cancer therapeutics, and we may not be able to develop any other product candidates. For example, we may not be successful in identifying genomic alterations that are oncogenic and are targeted for patient populations that result in sufficient enrollment size or present attractive commercial opportunities. Even if we are successful in building a pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval from the FDA, EMA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which would result in significant harm to our financial position and adversely affect our business. The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed. Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product candidate' s commercial potential. Even if approved, we may be required to conduct additional studies to verify or confirm the clinical benefits of our products. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and / or regulatory approval may be delayed for reasons beyond our control. Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials; • the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended adverse events, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; • the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval; • the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the clinical data of the clinical trial may fail to meet the level of statistical significance required to obtain approval of our product candidates by the FDA, EMA or other comparable foreign regulatory authorities; • we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that ~~a~~ **our** product ~~candidate~~ **candidates** ' ~~s~~ risk- benefit ~~ratio~~ **ratios** for ~~its~~ **their** proposed ~~indication~~ **indications** ~~is~~ **are** acceptable; • the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; • the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests required for our product candidates; • we may not obtain or maintain adequate funding to complete the clinical trial in a manner that is satisfactory to the FDA, EMA or other comparable foreign regulatory authorities; and • the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. We have only limited experience as a company in the conduct of clinical trials. We have only limited experience as a company in the conduct of clinical trials. In part because of this

lack of experience as a company and our limited infrastructure, we cannot be certain that our preclinical studies and clinical trials will begin or be completed on time, if at all. Large- scale clinical trials ~~would~~ require significant ~~additional~~ financial and management resources and ~~reliance~~ **we expect to rely** on third- party clinical investigators, CROs, and consultants **in connection with any large- scale clinical trials we conduct** . Relying on third- party clinical investigators, CROs and consultants may ~~force~~ **result in** us ~~to encounter~~ **encountering** delays that are outside of our control. We **also** may be unable to identify and contract with sufficient investigators, CROs and consultants on a timely basis or at all. There can be no assurance that we will be able to negotiate and enter into any necessary services agreement with CROs on terms that are acceptable to us on a timely basis or at all. We may not be able to submit INDs, CTAs or comparable applications to commence clinical trials on the timelines we expect, and even if we are able to, the FDA, EMA or any comparable foreign regulatory authority may not permit us to proceed. ~~We~~ **While we** have **submitted INDs** ~~initiated Phase 1 / 2 clinical trials~~ for **some of our product candidates** ~~NVL- 520 and NVL- 655. However~~ , we may not be able to submit INDs for ~~NVL- 330 or~~ any ~~future~~ **other** product candidates on the timelines we expect or such submissions may not take effect on the timeline that we anticipate or at all. For example, we may experience manufacturing delays or other delays with IND- enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that it will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to submit INDs, CTAs or comparable applications on the timelines we expect or to obtain regulatory approvals for our planned clinical trials may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely basis, if at all. Our product candidates may cause significant adverse events, toxicities or other undesirable adverse events when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences. If our product candidates are associated with undesirable adverse events or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs **,** we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable adverse events or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. Treatment- related adverse events could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly. ~~It~~ **There have been, and it** is likely that there will be **additional,** adverse events associated with the use of our product candidates as is typically the case with oncology drugs. Results of our studies or trials could reveal a high and unacceptable severity and prevalence of these or other adverse events. In such an event, our trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug- related adverse events could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, our product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory authorities. Our product candidates may be studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause adverse events that are unrelated to our product candidates but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients to be enrolled in our current or future clinical trials may die or experience major clinical events either during the course of our clinical trials or after participating in such trials for non- treatment related reasons. If significant adverse events are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable foreign regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse events. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early- stage trials have later been found to cause adverse events that prevented their further development. Even if the adverse events do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable adverse events may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early **-** stage clinical trials. Interim, **preliminary and** topline ~~and preliminary~~ data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. **We have** ~~From time to time, we may~~ publicly ~~disclose~~ **disclosed interim,** preliminary ~~, interim~~ or topline data from our preclinical studies and clinical trials **and we expect to do so in the future** . These interim updates are based on ~~a~~ preliminary ~~analysis~~ **analyses** of then- available data, and the results and related findings and

conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow- up evaluations. 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 **interim, preliminary or** topline results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. **Interim, preliminary and** ~~Topline~~ **topline** data also remain subject to audit and verification procedures that may result in the final data being materially different from the **interim,** preliminary **or topline** data we previously published. As a result, **interim, preliminary and** topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim **, preliminary and topline** data from clinical trials ~~that we may complete~~ are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim **, preliminary or topline** data and final data could significantly harm our business and prospects. Further, additional disclosure of interim **, preliminary or topline** data by us or by our competitors in the future could result in volatility in the price of our Class A common stock. In addition, the information we choose to publicly disclose regarding a particular study or trial is typically selected from a more extensive amount of available information. Investors may not agree with what we determine is the material or otherwise appropriate information to include in our public disclosures, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the **interim,** preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. If we experience delays or difficulties in the enrollment or maintenance of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented. 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 to such trial' s conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. We ~~will~~ utilize genomic profiling of patients' tumors to identify suitable patients for recruitment into our clinical trials for NVL- 520 and NVL- 655 **and expect to do so for our planned clinical trials of NVL- 330** . For these product candidates, we seek patients with specific genomic alterations that our product candidates are designed to precisely target. We cannot be certain (i) how many patients will have the requisite genomic alterations that qualify for inclusion in our clinical trials, (ii) that the number of patients enrolled in each program will suffice for regulatory approval or (iii) if regulatory approval is obtained, whether each specific ROS1 **,** ~~fusion or~~ ALK ~~fusion~~ **or HER2 alteration** will be included in the approved drug label. Additionally, we face competition, including from large pharmaceutical companies with significantly more resources than us, for enrollment of our precisely ~~target~~ **targeted** patient ~~population~~ **populations** , which may impact our ability to successfully recruit patients for our clinical trials. If our strategies for patient identification and enrollment prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for our product candidates. Patient enrollment may be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Patient enrollment for our current or future clinical trials may be affected by other factors, including: • size and nature of the patient population; • severity of the disease under investigation; • availability and efficacy of approved drugs for the disease under investigation; • patient eligibility criteria for the trial in question as defined in the protocol, including biomarker- driven identification and / or certain highly- specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have a biomarker- driven patient eligibility criteria; • perceived risks and benefits of the product candidate under study; • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or other product candidates being investigated for the indications we are investigating; • clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials; • patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • proximity and availability of clinical trial sites for prospective patients; and • the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late- stage cancer patients, will not survive the full terms of the clinical trials. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow- up periods. We have never commercialized a product candidate as a company before and currently lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators. We have never commercialized a product candidate as a company. We may license certain rights with respect to our product candidates to collaborators, and, if so, we will rely on the assistance and guidance of those collaborators. For product candidates for 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 our product candidates, 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 candidates, ensuring regulatory compliance of our company, employees and third parties 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 our product candidates upon approval. 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 our product candidates, we may not generate revenue from them or be able to reach or sustain profitability. ~~The ongoing COVID- 19 pandemic could adversely impact our business, including our clinical trials and preclinical studies. The ongoing COVID- 19 pandemic could adversely impact our business, including our clinical trials and preclinical studies. As the pandemic continues and new variants of the virus continue to emerge, we may experience disruptions that could severely impact our business and clinical trials, including: • delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • delays or difficulties in enrolling and retaining patients in any clinical trials who are at a higher risk of severe illness or death due to disease; • diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials; • limitations in resources that would otherwise be focused on the conduct of our business, our preclinical studies or our clinical trials; • delays in receiving approval from regulatory authorities to initiate our clinical trials; • delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials; and • refusal of the FDA, EMA or other regulatory authorities to accept data from clinical trials in affected geographies outside of their respective jurisdictions. Additionally, certain third parties may experience continued business disruptions, which could limit our ability to conduct our business in the manner and on the timelines presently planned. For example, as a result of the COVID- 19 pandemic, there have been delays in the procurement of materials and our manufacturing supply chain for our product candidates. While these delays have not had a material impact on our development timelines or processes to date, they could delay or otherwise impact our preclinical studies and clinical trials in the future. In addition, certain clinical trial sites for product candidates similar to ours have experienced, and others may experience in the future, delays in collecting, receiving and analyzing data from patients enrolled in clinical trials due to limited staff at such sites, limitation of on- site visits by patients, or patients' reluctance to visit the clinical trial sites during the pandemic and we may experience similar delays. CROs have also made certain adjustments to the operation of such trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA and may need to make further adjustments in the future that could impact the timing or enrollment of our clinical trials. Many of these would increase costs, and may have negative effects on the enrollment, progress and completion of these trials and the findings from these trials. On January 30, 2023, the Biden administration announced that it will end the public health emergency declarations related to COVID- 19 on May 11, 2023. On January 31, 2023, the FDA indicated that it would soon issue a Federal Register notice describing how the termination of the public health emergency will impact the FDA' s COVID- 19 related guidance, including the clinical trial guidance and updates thereto. At this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates. The global outbreak of COVID- 19 continues to evolve. While the extent of the impact of the continued COVID- 19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID- 19 pandemic could have a material negative impact on our business, financial condition and operating results. To the extent the ongoing COVID- 19 pandemic adversely affects our business, financial condition and operating results, it may also have the effect of heightening many of the risks described in this " Risk Factors " section.~~ We have limited resources and are currently focusing our efforts on the development of NVL- 520, NVL- 655 and NVL- 330 in particular indications and advancing our discovery programs. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable. We are currently focusing our resources and efforts on our lead product candidates, NVL- 520 and NVL- 655, for advanced ROS1- positive NSCLC and other solid tumors and advanced ALK- positive NSCLC and other solid tumors, respectively, on our NVL- 330 product candidate **for advanced HER2- altered NSCLC** , and on advancing our discovery programs. As a result, because we have limited resources, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may 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 activities for NVL- 520, NVL- 655, NVL- 330 and our discovery programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for NVL- 520, NVL- 655, NVL- 330 or any future product candidates we identify through our discovery programs, we may enter into collaboration, licensing or other strategic arrangements with the effect of relinquishing valuable rights in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. We face substantial competition which may result in others discovering, developing or commercializing products before or more successfully than we do. The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of product candidates are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our product candidates may need to compete with drugs physicians use off- label to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our product candidates. In particular, there is intense competition in the field of oncology. We have competitors both in the U. S. and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start- up companies, universities and other

research institutions. We also compete with these organizations to recruit and retain qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. We expect to face competition from existing products and products in development for each of our lead programs and in particular, our competitors that are developing product candidates often have the advantage of significant financial resources. For NVL- 520, there are currently ~~two~~ **three** ROS1- targeted kinase inhibitors approved **by the FDA** for use in ~~first- line,~~ TKI naïve ROS1- positive NSCLC: crizotinib ~~and~~ **,** entrectinib **and repotrectinib** . ~~Both have~~ **Crizotinib has** also received approval for treatment of ALK- positive NSCLC. Ceritinib and lorlatinib are considered as other therapies recommended for use in ROS1- positive NSCLC patients according to NCCN guidelines. Lorlatinib is a dual ALK / ROS1 inhibitor that has received marketing approval for the treatment of ALK- positive NSCLC, and has demonstrated CNS activity as reported in its prescribing information. ~~Repotrectinib is a dual TRK / ROS1 inhibitor that is in development and has demonstrated clinical activity in ROS1- positive NSCLC patients but also retains potent TRK inhibition at clinically relevant concentrations.~~ AnHeart Therapeutics' taletrectinib is a dual TRK / ROS1 inhibitor and is in development for patients with ROS1- positive NSCLC. For NVL- 655, there are five ~~currently approved~~ ALK inhibitors **approved by the FDA** for the treatment of ALK- positive NSCLC: crizotinib, lorlatinib, ceritinib, alectinib, and brigatinib. All five have line- agnostic approvals for the treatment of ALK- positive NSCLC patients, including for patients who are TKI naïve. Additionally, lorlatinib has demonstrated activity in patients that have progressed on crizotinib, alectinib, or ceritinib. For NVL- 330, there is currently one ~~approved~~ antibody- drug conjugate **approved by the FDA** for the treatment of HER2 **mutant** ~~Exon 20 mutation- positive~~ NSCLC: fam- trastuzumab deruxtecan- nxki. There are no kinase inhibitors approved for this patient population. Other kinase inhibitors in development for patients with HER2 ~~Exon 20~~ mutant ~~- positive~~ NSCLC include Shanghai Hengrui Pharmaceutical Co., Ltd.' s pyrotinib, Boehringer Ingelheim Pharmaceuticals, Inc.' s **zongertinib (** BI- 1810631 **)** , and Enliven Therapeutics' ELVN- 002. Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology product candidates. These companies also have significantly greater research and marketing capabilities than we do and may also have product candidates that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make the product candidates that we develop obsolete. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing product candidates in our field before we do. Our potential commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe adverse events, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop. Physicians may be more willing to prescribe our competitors' products for various reasons, and may rely on guidelines related to treatment of patients issued by medical societies, industry groups or other organizations, which may not include, and may never include, our products. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development and marketing more complicated. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected. The manufacture of drugs is complex, and our third- party manufacturers may encounter difficulties in production. If any of our third- party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented. Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Slight deviations anywhere in the manufacturing process, including filling, labelling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our ~~manufacturer~~ **manufacturers** , such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Contaminations can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our third- party manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Changes in methods of product candidate manufacturing or formulation may result in additional costs or

delay. As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, we may introduce an alternative formulation of one or more of our product candidates during the course of our clinical trials. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and impair our ability to generate revenue. Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success. Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third- party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including: • the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments; • the timing of market introduction of the product candidate as well as competitive products; • the clinical indications for which a product candidate is approved; • restrictions on the use of product candidates in the labelling approved by regulatory authorities, such as boxed warnings or contraindications in labelling, or a REMS, if any, which may not be required of alternative treatments and competitor products; • the potential and perceived advantages of our product candidates over alternative treatments; • the cost of treatment in relation to alternative treatments; • the availability of coverage and adequate reimbursement by third- party payors, including government authorities; • willingness of physicians to use our product candidates, if approved, in lieu of (or ~~as a second- line treatment~~ in conjunction with) other approved therapies; • the availability of an approved product candidate for use as a combination therapy; • relative convenience and ease of administration; • the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests; • the effectiveness of sales and marketing efforts; • unfavorable publicity relating to our product candidates; and • the approval of other new therapies for the same indications. If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted. The market opportunities for any product candidates we develop, if approved, may be limited to certain smaller patient subsets and may be smaller than we estimate them to be. When cancer is detected early (referred to as localized disease), conventional treatments , which include chemotherapy, hormone therapy, surgery and radiation therapy and / or selected targeted therapies , may be adequate to cure the patient in many cases. However, once cancer has spread to other areas (advanced or metastatic disease), cancer treatments may not be sufficient to provide a cure but often can significantly prolong life without curing the cancer. First- line therapies designate treatments that are initially administered to patients with advanced or metastatic disease, while second- and third- line therapies are administered to patients when the prior therapies lose their effectiveness. The FDA, EMA and other regulatory bodies often approve cancer therapies for a particular line of treatment. Typically, drug approvals are initially granted for use in later lines of treatment, but with additional evidence of significant efficacy from clinical trials, biopharmaceutical companies can successfully seek and gain approval for use in earlier lines of treatment. We plan to initially seek approval of NVL- 520, NVL- 655, NVL- 330 and any other future product candidates in most instances for previously treated patients with advanced or metastatic cancer where at least one prior therapy has limited clinical benefit or where tumors have developed resistance to such therapy. For those product candidates that prove to be sufficiently safe and effective, if any, we would potentially expect to seek approval ultimately as a first line TKI therapy. There is no guarantee that our product candidates, even if approved for previously treated patients would be approved for an earlier line of therapy, and prior to any such approvals we may have to conduct additional clinical trials that may be costly, time- consuming and subject to risk. Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new data and studies may change the estimated incidence or prevalence of the cancers that we are targeting, especially if new therapies that are approved while we advance our product candidates affect the treatment paradigm and / or the size of the target population. The potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type. Even if we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. Any product candidates we develop may become subject to unfavorable third- party coverage and reimbursement practices, as well as pricing regulations. Patients rely on insurance coverage by third- party payors (third- party payors include Medicare and Medicaid (government payors) and commercial insurance companies such as Blue Cross Blue Shield, Humana, Cigna, etc.), to pay for products. The availability and extent of coverage and adequate reimbursement by third- party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third- party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the U. S. and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third- party payors. No uniform policy

exists for coverage and reimbursement in the U. S. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. 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 reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. There is significant uncertainty related to third- party payor coverage and reimbursement of newly approved products. In the U. S., for example, principal decisions about reimbursement for new products are typically made by the CMS, an agency within ~~the~~ HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third- party payors often follow CMS' s decisions regarding coverage and reimbursement to a substantial degree. However, one third- party payor' s determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time- consuming and costly. Factors payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost- effective; and (v) neither experimental nor investigational. This process will require us to provide scientific and clinical support for the use of our products to each third- party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. As federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that our products, if approved, will be covered by private or public payors, and if covered, whether the reimbursement will be adequate or competitive with other marketed products. Such other actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and health care costs, which could negatively impact coverage and reimbursement for our products if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development. For further discussion, see " — Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for our product candidates; " and " — The prices of prescription pharmaceuticals in the U. S. and foreign jurisdictions are the subject of considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed for marketing. " 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. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third- party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA- approved drugs for a particular indication. We may need to conduct expensive pharmaco- economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved. Outside the U. S., the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the U. S. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U. S., the reimbursement for our products may be reduced compared with the U. S. and may be insufficient to generate commercially reasonable revenue and profits. If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third- party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third- party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition. Our business exposes us to significant product liability and other risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability and other claims or incidents, such as cyber incidents and breaches, could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the

merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management' s time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability and other insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to advancing our product candidates into ~~clinical trials~~ **later stages of development** or marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial, product liability, and other types of insurance (such as cyber insurance) is becoming increasingly expensive and difficult to obtain. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability or other claims or incidents, including data breach and incidents, that could have an adverse effect on our business and financial condition. Risks related to regulatory approval and other legal compliance matters We may be unable to obtain U. S. or foreign regulatory approval and, as a result, may be unable to commercialize our product candidates. Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labelling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the U. S. and in many foreign jurisdictions before a new drug can be approved for marketing. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them. We have not conducted, managed or completed large- scale or pivotal clinical trials nor managed the regulatory approval process with the FDA, EMA or any other regulatory authority. The time required to obtain approvals from the FDA, EMA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in applicable FDA, EMA or other regulatory policy during the period of drug development, clinical trials and regulatory review. • the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective or have undesirable or unintended adverse events, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use ~~; • we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate' s risk- benefit ratio for its proposed indication is acceptable~~ ; • the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labelling or other restrictions. In addition, the FDA has the authority to require a REMS plan as part of approving a NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe- use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third- party payors. We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third- party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. We may develop our current or future product candidates in combination with other therapies, which would expose us to additional risks. We may develop our current or future product candidates in combination with one or more currently approved cancer therapies or therapies in development. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially. We may also evaluate our current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third- party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our

development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. ~~The~~ **We have conducted and intend to continue conducting certain of our clinical trials globally. However, the** FDA ~~, EMA~~ and other ~~comparable~~ foreign **equivalents** ~~regulatory authorities~~ may not accept data from **such** trials **, in which case our development plans may be delayed, which could materially harm our business. We have** conducted **and intend to continue** ~~in locations outside of their jurisdiction. We conduct~~ **conducting certain of our** clinical trials **globally** ~~of our product candidates in the U. S. and internationally~~ . The acceptance **by the FDA or other regulatory authorities** of study data ~~by the FDA, EMA or other comparable foreign regulatory authority~~ from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions **or may not be accepted at all** . In cases where data from **foreign** ~~U. S.~~ clinical trials are intended to serve as the **sole** basis for marketing approval in the **U. S., the FDA will generally not approve the application on the basis of** foreign ~~countries outside~~ **data alone unless (i) the data are applicable to** the U. S. ~~,~~ **population and U. S. medical practice; (ii)** the ~~standards for~~ **trials were performed by** clinical **investigators of recognized competence and pursuant to GCP regulations; 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 inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well- designed and well- conducted in accordance with GCP requirements, and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign** trials **would** ~~and approval may~~ be ~~different~~ **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 **comparable** ~~U. S. or~~ foreign regulatory authority ~~would~~ **will** accept data from trials conducted outside of ~~its~~ **the U. S. or the** applicable jurisdiction. If the FDA ~~, EMA~~ or any ~~applicable~~ **comparable** 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, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction. **Conducting clinical trials outside the U. S. also exposes us to additional risks, including risks associated with: • additional foreign regulatory requirements; • foreign exchange fluctuations; • compliance with foreign manufacturing, customs, shipment and storage requirements; • cultural differences in medical practice and clinical research; • diminished protection of intellectual property in some countries; and • interruptions or delays in our trials resulting from geopolitical events, including civil or political unrest or military conflicts.** Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the U. S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U. S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed. ~~Additionally~~ **Further** , ~~on June 23, 2016, the electorate~~ **we could face heightened risks with respect to obtaining marketing authorization** in the U. K. ~~voted in favor~~ **as a result** of ~~leaving~~ **the withdrawal of the U. K. from** the EU ~~(~~ **, commonly referred to as** Brexit ~~)~~ . **The** ~~Following protracted negotiations, the U. K. left the EU on January 31, 2020, and a transition period to December 31, 2020, was established to allow the U. K. and the EU to negotiate the U. K.' s withdrawal. As a result, effective January 1, 2021, the~~ U. K. is no longer part of the European Single Market and EU Customs Union. **As of** ~~A co- operation agreement was signed between the U. K. and the EU in December 2020, which was applied provisionally beginning on~~ January 1, 2021, ~~and entered into force on May 1, 2021. The agreement addresses trade, economic arrangements, law enforcement, judicial cooperation, and a governance framework including procedures for dispute resolution, among other~~ -- **the** ~~things. As both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal. As of January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (~~ MHRA ~~)~~ became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland, and Wales under domestic law, whereas ~~Northern Ireland will continue to be subject to EU rules~~ under **the terms of** the Northern Ireland Protocol **, Northern Ireland is currently subject to EU rules** . The **U** ~~MHRA will rely on the Human Medicines Regulations 2012 (SI 2012 / 1916) (as amended) (HMR) as the basis for regulating medicines~~ . **K. and** ~~The HMR has incorporated into the domestic law of the body of~~ EU ~~law instruments governing~~ **have, however, agreed to the Windsor Framework, which fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of** medicinal products **in** ~~that pre- existed prior to~~ the U. K. **Once implemented, the changes introduced by the Windsor Framework will make the MHRA responsible for approving all medicinal products destined for the U. K. market (i. e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving**

medicinal products destined for Northern Ireland. In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission ' s ~~withdrawal from~~ **proposal for revision of several legislative instruments related to medicinal products (potentially reducing** the ~~EU~~ **duration of regulatory data protection, revising the eligibility for expedited pathways, etc** . ~~Since~~ **) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have** a significant ~~proportion of~~ **impact on** the ~~regulatory framework for~~ pharmaceutical **industry** ~~products in the U. K. covering the quality, safety,~~ and ~~efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of~~ our **business** ~~product candidates~~ in the ~~U. K. For example, the U. K. is no longer~~ -- **long term** ~~covered by the centralized procedures for obtaining EU- wide marketing authorization from the EMA, and a separate marketing authorization will be required to market our product candidates in the U. K. Until December 31, 2023, it is possible for the MHRA to rely on a decision taken by the European Commission on the approval of a new marketing authorization via the centralized procedure~~ . Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the U. K. for our product candidates, which could significantly and materially harm our business **. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our product candidates may be withdrawn. If we fail to comply with the applicable regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed** . Even if our product candidates receive regulatory approval, they will be subject to significant post- marketing regulatory requirements and oversight. Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and ~~on- going~~ **ongoing** surveillance to monitor the safety and efficacy of the product candidate, 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 and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, 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, EMA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labelling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as ~~on- going~~ **ongoing** compliance with cGMPs and good clinical practices (GCP) for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the U. S. prior to being imported or offered for import into the U. S. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including: • delays in or the rejection of product approvals; • restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; • restrictions on the products, manufacturers or manufacturing process; • warning or untitled letters; • civil and criminal penalties; • injunctions; • suspension or withdrawal of regulatory approvals; • product seizures, detentions or import bans; • voluntary or mandatory product recalls and publicity requirements; • total or partial suspension of production; • imposition of restrictions on operations, including costly new manufacturing requirements; • revisions to the labelling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings; • imposition of a REMS, which may include distribution or use restrictions; and • requirements to conduct additional post- market clinical trials to assess the safety of the product. **Finally, our ability to develop and market new drug products may be impacted by ongoing litigation challenging the FDA' s approval of mifepristone. Specifically, on April 7, 2023, the U. S. District Court for the Northern District of Texas stayed the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. In reaching that decision, the district court made a number of findings that may negatively impact the development, approval and distribution of drug products in the U. S. Among other determinations, the district court held that plaintiffs were likely to prevail in their claim that the FDA had acted arbitrarily and capriciously in approving mifepristone without sufficiently considering evidence bearing on whether the drug was safe to use under the conditions identified in its labeling. Further, the district court read the standing requirements governing litigation in federal court as permitting a plaintiff to bring a lawsuit against the FDA in connection with its decision to approve an NDA or establish requirements under a REMS based on a showing that the plaintiff or its members would be harmed to the extent that FDA' s drug approval decision effectively compelled the**

plaintiffs to provide care for patients suffering adverse events caused by a given drug. On April 12, 2023, the district court decision was stayed, in part, by the U. S. Court of Appeals for the Fifth Circuit. Thereafter, on April 21, 2023, the U. S. Supreme Court entered a stay of the district court' s decision, in its entirety, pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit and the disposition of any petition for a writ of certiorari to the U. S. Supreme Court. The Court of Appeals for the Fifth Circuit held oral argument in the case on May 17, 2023 and, on August 16, 2023, issued its decision. The Court of Appeals declined to order the removal of mifepristone from the market, finding that a challenge to the FDA' s initial approval in 2000 is barred by the statute of limitations, but the Court of Appeals did hold that the plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that the FDA authorized in 2016 and 2021 were arbitrary and capricious. On September 8, 2023, the Department of Justice and a manufacturer of mifepristone filed petitions for a writ of certiorari, asking the U. S. Supreme Court to review the Court of Appeals decision. On December 13, 2023, the U. S. Supreme Court granted these petitions for writ of certiorari for the Court of Appeals decision The FDA, EMA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. The FDA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses. If any of our product candidates are approved and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability. The FDA, EMA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted in the U. S. for uses that are not approved by the FDA as reflected in the product' s approved labelling, or in other jurisdictions for uses that differ from the labelling or uses approved by the applicable regulatory authorities. While physicians may prescribe products for off- label uses, the FDA, EMA and other regulatory authorities actively enforce laws and regulations that prohibit the promotion of off- label uses by companies, including promotional communications made by companies' sales force with respect to off- label uses that are not consistent with the approved labelling, and a company that is found to have improperly promoted off- label uses may be subject to significant civil, criminal and administrative penalties. **Notwithstanding the regulatory restrictions on off- label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non- misleading, and non- promotional scientific communications concerning their products in certain circumstances. For example, in October 2023, the FDA published draft guidance outlining the agency' s non- binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths, weaknesses, validity and utility of the information about the unapproved use. In addition, under recent guidance from the FDA and the PIE Act, signed into law as part of the CCA, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA' s various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.** If we are found to have promoted such off- label uses, we may become subject to significant liability. The U. S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. If we are required by the FDA, EMA or comparable regulatory authority to obtain clearance or approval of a companion diagnostic test in connection with approval of any of our product candidates or a group of therapeutic products, and we do not obtain or we face delays in obtaining clearance or approval of a diagnostic test, we may not be able to commercialize the product candidate and our ability to generate revenue may be materially impaired. If we are required by the FDA, EMA or a comparable regulatory authority to obtain clearance or approval of a companion diagnostic test in connection with approval of any of our product candidates, such companion diagnostic test would be used during our more advanced phase clinical trials as well as in connection with the commercialization of our product candidates. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to ensuring the safe and effective use of a novel therapeutic product or new indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared. In certain circumstances (for example, when a therapeutic product is intended to treat a serious or life- threatening condition for which no satisfactory available therapy exists or when the labelling of an approved product needs to be revised to address a serious safety issue), however, the FDA may approve a therapeutic product without the prior or contemporaneous marketing authorization of a companion diagnostic. In this case, approval of a companion diagnostic may be a post- marketing requirement or commitment. Co- development of companion diagnostics and therapeutic products is critical to the advancement of precision medicine. Whether initiated at the outset of development or at a later point, co- development should generally be

conducted in a way that will facilitate obtaining contemporaneous marketing authorizations for the therapeutic product and the associated companion diagnostic. If a companion diagnostic is required to identify patients who are most likely to benefit from receiving the product, to be at increased risk for serious adverse events as a result of treatment with a particular therapeutic product, or to monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness, then the FDA has required marketing approval of all companion diagnostic tests essential for the safe and effective use of a therapeutic product for cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any future diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization in those countries. The approval of a companion diagnostic as part of the therapeutic product' s ~~labelling~~ **labeling** limits the use of the therapeutic product to only those patients who express the specific genomic alteration or mutation alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires clearance or approval of a companion diagnostic for any of our product candidates, whether before, concurrently with approval, or post- approval of the product candidate, we, and / or future collaborators, may encounter difficulties in developing and obtaining clearance or approval for these companion diagnostics **. The process of obtaining or creating such diagnostic is time consuming and costly. The FDA previously has required in vitro companion diagnostics intended to select the patients who will respond to a product candidate to obtain PMA, simultaneously with approval of the therapeutic candidate. The PMA process, including the gathering of preclinical and clinical data and the submission and review by the FDA, can take several years or longer. It involves a rigorous pre- market review during which the sponsor must prepare and provide FDA with reasonable assurance of the device' s safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. After a device is placed on the market, it remains subject to significant regulatory requirements, including requirements governing development, testing, manufacturing, distribution, marketing, promotion, labeling, import, export, record- keeping, and adverse event reporting** . Any delay or failure by us or third- party collaborators to develop or obtain regulatory clearance or approval of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates. Further, in April 2020, the FDA issued new guidance on developing and ~~labelling~~ **labeling** companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader ~~labelling~~ **labeling** claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. This guidance and future issuances from the FDA, EMA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and could result in delays in regulatory clearance or approval or a change in the determination for whether or not a companion diagnostic is still required for our product candidates. We may be required to conduct additional studies to support a broader claim or more narrowed claim for a subset population. Also, to the extent other approved diagnostics are able to broaden their ~~labelling~~ **labeling** claims to include any of our future approved product candidates covered indications, we may no longer need to continue our companion diagnostic development plans or we may need to alter those companion diagnostic development strategies, which could adversely impact our ability to generate revenue from the sale of our companion diagnostic test. Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining clearance or approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity / specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory clearance or approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory clearance or approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and / or delay the co- development or commercialization of our companion diagnostic and therapeutic product candidates. Where appropriate, we plan to pursue approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval. Where appropriate, we plan to pursue accelerated development strategies in areas of medical need. We may seek an accelerated approval pathway for ~~our~~ one or more of our product candidates from the FDA,

EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the ~~FDCA~~ **Federal Food, Drug, and Cosmetic Act**, and the FDA' s implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verify and describe the drug' s clinical benefit. If such post- approval studies fail to confirm the drug' s clinical benefit, the FDA may withdraw its approval of the drug. With passage of ~~the~~ FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to ~~:~~ require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post- approval studies to the FDA every six months (until the study is completed) ~~;~~ **,** and use expedited procedures to withdraw accelerated approval of an NDA or BLA after the confirmatory trial fails to verify the product' s clinical benefit. Further, FDORA requires the FDA to publish on its website " the rationale for why a post- approval study is not appropriate or necessary " whenever it decides not to require such a study upon granting accelerated approval. **More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life- threatening nature of cancer. Although single- arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. While a randomized controlled trial is the preferred approach, the guidance states that there can be circumstances wherein a single- arm trial is appropriate in the development of a drug for accelerated approval. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. While this guidance is currently only in draft form and will not be legally binding even when finalized, we will need to consider the FDA' s guidance if we seek accelerated approval for any of our products in the future and work with the FDA on this approach. In the EU, a " conditional " marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a " standard " marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.** Prior to seeking accelerated approval, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or ~~under~~ **any** ~~another~~ -- **other form of** expedited **development** ~~regulatory designation (i. e.~~ , **review** ~~Fast Track designation, Breakthrough Therapy designation~~ or **approval** ~~orphan drug designation)~~ , there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace. We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review in the U. S., and PRIME (priority medicines) in the EU, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process. **NVL- 520 has received FDA Breakthrough Therapy designation for the treatment of patients with ROS1- positive NSCLC who have previously been treated with two or more prior ROS1 TKIs.** We may seek certain designations for one or more of our **other** product candidates **or other designations for NVL- 520** 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 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, early and frequent interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development. **Sponsors may also have greater interactions with the FDA and the FDA may initiate review of sections of**

the NDA of a product candidate with Breakthrough Therapy designation before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of data submitted by the sponsor, that a product with Breakthrough Therapy designation may be effective. We may also seek Fast Track designation for one or more of our product candidates. 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~~ **Like with Breakthrough Therapy designation, sponsors with** Fast Track products ~~, sponsors~~ may have greater **FDA** interactions ~~with the FDA~~ and the FDA may initiate review of sections of a Fast Track product' s NDA before the application is complete ~~. This rolling review may be available~~ if **it** ~~the FDA~~ determines, after **its** preliminary **data** evaluation ~~of data submitted by the sponsor~~ , that **the** ~~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 intended to treat a serious condition and, if approved, offers a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation shortens the goal for the FDA to review an application within six months, rather than the standard review period of ten months. These designations require a sponsor to submit an application for review and approval by 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. In addition, even if ~~one or more of~~ our product candidates ~~qualifies~~ **qualify** 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. In the EU, we may seek PRIME for some of our product candidates in the future. PRIME is a voluntary program launched by the EMA that is aimed at enhancing the scientific and regulatory support for the development and accelerated assessment of new product candidates that target an unmet medical need. PRIME is aimed to offer early and proactive support to sponsors to optimize the generation of robust data on the product' s benefits and risks and enable accelerated regulatory assessment of new marketing applications. To be eligible for PRIME, a product candidate must meet the eligibility criteria in respect to its potential to offer a major therapeutic advantage over existing treatments, or benefit patients who do not have any treatment options. The benefits of PRIME include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. We may apply for PRIME and it may not be granted. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA' s grant of a marketing authorization. We may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products. Regulatory authorities in some jurisdictions, including the U. S. and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the U. S., or a patient population greater than 200, 000 in the U. S. where there is no reasonable expectation that the cost of researching and developing the drug will be recovered from sales in the U. S. Our target indications may include diseases with large patient populations or may include orphan indications. ~~However,~~ **NVL- 520 has received orphan drug designation for ROS1- positive NSCLC. NVL- 655 has received orphan drug designation for ALK- positive NSCLC.** ~~there~~ **There** can be no assurances that we will be able to obtain orphan ~~designations~~ **designation** for our **other current** product candidates **or candidates we may discover and develop in the future** . In the U. S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product candidate is entitled to orphan drug exclusivity. Orphan drug exclusivity in the U. S. provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan- designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the U. S. may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. 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 shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable

to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to Priority Review. The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term " same disease or condition " means the designated " rare disease or condition " and could not be interpreted by the FDA to mean the " indication or use. " Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the " indication or use. " Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court' s order, the FDA will continue to apply its existing regulations tying orphan- drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for our product candidates. In the U. S. and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed. In March 2010, President Obama signed into law the PPACA. Since enactment of the PPACA, there have been and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Act in 2017, Congress repealed the " individual mandate. " The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. **On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the PPACA brought by several states without specifically ruling on the constitutionality of the PPACA. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results.** Other legislative changes have been adopted since the PPACA was enacted, including aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013 and will remain in effect through 2031. Under current legislation, the actual reductions in Medicare payments may vary up to 4 % **. The CAA, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the CAA delays the 4 % Statutory Pay- As- You- Go Act of 2010 (PAYGO) sequester for two years, through the end of calendar year 2024. Triggered by the enactment of the American Rescue Plan Act of 2021, the 4 % cut to the Medicare program would have taken effect in January 2023. The CAA' s health care offset title includes Section 4163, which extends the 2 % Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031** . The American Taxpayer Relief Act of 2012 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. Further, with passage of the IRA in August 2022, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single- source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. In addition, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The **IRA** ~~new law~~ also caps Medicare out- of- pocket drug costs at an estimated $ 4, 000 a year in 2024 and, thereafter beginning in 2025, at $ 2, 000 a year. These laws and other healthcare reform measures may result in additional reductions in Medicare and other healthcare funding and otherwise affect the reimbursement we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product is prescribed or used. We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in coverage and payments from private payors. Accordingly, the implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. The prices of prescription pharmaceuticals have been the subject of considerable discussion in the U. S. There have been several recent U. S. Congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products, and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician- administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, the CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence- based care. In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a SIP to import certain prescription drugs from Canada into the U. S. ~~The final rule is currently~~ **That regulation was challenged in a lawsuit by** the **PhRMA** ~~subject of~~

~~ongoing litigation,~~ but ~~at least six~~ **the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Nine** states (~~Vermont,~~ Colorado, Florida, Maine **, New Hampshire** , New Mexico, **North Dakota, Texas, Vermont** and **Wisconsin** ~~New Hampshire~~) have passed laws allowing for the importation of drugs from Canada ~~with~~ **. Certain of** ~~the~~ **these** ~~intent of developing~~ **states have submitted** ~~SIPs~~ **SIP proposals** ~~for review~~ and **are awaiting FDA** approval ~~by~~ **. On January 5, 2023,** the FDA **approved Florida' s** ~~. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to~~ plan ~~sponsors under Part D, either directly or~~ **for Canadian drug importation** ~~through pharmacy benefit managers, unless the price reduction is required by law~~ . The final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point- of- sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but ~~with passage of the Inflation Reduction Act~~ has been delayed by Congress to January 1, 2032. In September 2021, acting pursuant to an executive order signed by President Biden, ~~the~~ HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments. **On** ~~More recently, on~~ August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of ~~the~~ HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single- source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high- cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out- of- pocket drug costs at an estimated $ 4, 000 a year in 2024 and, thereafter beginning in 2025, at $ 2, 000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or " catastrophic period " of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100 % of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co- insurance and co- payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out- of- pocket expenses, each of which could have potential pricing and reporting implications. **On June 6, 2023, Merck & Co., Inc. filed a lawsuit against HHS and CMS asserting that, among other things, the IRA' s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U. S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.** Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition. At the **U. S.** state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription product and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. In **addition** ~~the EU~~ , **in some** ~~similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In many~~ countries,

including ~~those~~ **member states** of the EU, the pricing of prescription pharmaceuticals is subject to governmental control ~~and access~~. In these countries, pricing negotiations with governmental authorities can take ~~considerable~~ **a significant amount of** time after the receipt of marketing approval for a product. ~~To obtain~~ **In addition, there can be considerable pressure by governments and other stakeholders on prices and** reimbursement ~~or~~ **levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate** pricing ~~approval~~ **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, and** in **certain instances render commercialization in certain markets infeasible or disadvantageous from a financial perspective. In** some countries, we or our collaborators may be required to conduct a clinical trial **or other studies** that ~~compares~~ **compare** the cost- effectiveness of our ~~product~~ **products** to other available ~~therapies~~ **products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third party payors or government authorities may lead to further pressure on the prices or reimbursement levels**. If reimbursement of our products is unavailable or limited in scope or amount **,** or if pricing is set at unsatisfactory levels, **the commercial launch of our products could be delayed, possibly for lengthy periods of time, we or our collaborators may not launch at all in a particular country, we may not be able to recoup our investment in one or more products, and there could be a material adverse effect on** our business ~~could be materially harmed~~. We are or may become subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations. There are multiple privacy and data security laws that may impact our business activities in the U. S. and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry generally, for example, under HIPAA, HHS has issued regulations to protect the privacy and security of protected health information (PHI) used or disclosed by specific covered entities including certain healthcare providers, health plans and healthcare clearinghouses. We are not currently classified as a covered entity or business associate under HIPAA. Thus, we are not directly subject to HIPAA' s requirements or penalties. The healthcare providers, including certain research institutions from which we may obtain patient or subject health information, may be subject to privacy, security, and breach notification requirements under HIPAA. Additionally, any person may be prosecuted under HIPAA' s criminal provisions either directly or under aiding- and- abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face criminal penalties if we knowingly receive individually identifiable health information from a HIPAA covered entity, business associate or subcontractor that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information. In addition, ~~in the future,~~ we may maintain sensitive personally identifiable information, including health and genetic information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement such programs. As such, **in addition to risks and obligations related to HIPAA,** we **also** may be subject to various state laws regulating the use or disclosure of this information or requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic information laws may apply directly to our operations and / or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Individuals from whom we or our collaborators may obtain health information, as well as the healthcare providers who may share this information with us, may have statutory or contractual rights that limit the ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. Additionally, the collection and use of personal data, including data concerning health, in the EU is governed by the GDPR, which extends the geographical scope of EU data protection law to non- EU entities under certain conditions and imposes substantial obligations upon companies and new rights for individuals, as discussed below in " — Processing of personal data is governed by restrictive laws and regulations in the jurisdictions in which we operate. " Brexit may adversely impact our ability to obtain regulatory approvals for our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU. Inadequate funding for the FDA, the SEC and other U. S. government agencies or the EMA or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA, EMA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA and other regulators have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U. S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to

furlough critical employees and stop critical activities. ~~If~~ **In addition, disruptions may result in events similar to the COVID-19 pandemic. During the COVID- 19 pandemic, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the U. S. facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities. Accordingly, if** a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations ~~. In 2020 and 2021 a number of companies announced receipt of CRLs due to the FDA' s inability to complete required inspections for their applications. As of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the ongoing COVID- 19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre- approval inspection or an inspection of clinical sites is required and due to the ongoing COVID- 19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets~~ . If our product candidates are licensed for marketing and receive federal healthcare reimbursement, any relationships we may have with healthcare providers will be subject to applicable healthcare fraud and abuse laws and regulations, which could expose us to criminal and civil penalties and exclusion from participation in government healthcare programs. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any products for which we are able to obtain marketing approval. Any arrangements we have with healthcare providers, third- party payors and customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. The laws and regulations may constrain the business or financial arrangements and relationships through which we conduct clinical research, market, sell and distribute any products for which we obtain marketing approval. These include the following: • Anti- Kickback Statute. The federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward or in return for, either the referral of an individual for or the purchase, lease or order of a good, facility, item or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. • False Claims Laws. The federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions against individuals or entities for, among other things, knowingly presenting or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per- claim penalties. • HIPAA. HIPAA imposes criminal and civil liability for, among other things, executing a scheme or making materially false statements in connection with the delivery of or payment for health care benefits, items or services. Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations on covered entities and their business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information. • Transparency Requirements. The federal Physician Payments Sunshine Act 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 specific exceptions, to report annually to CMS information related to payments or transfers of value made to physicians, other healthcare providers and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. • Analogous State and Foreign Laws. Analogous state and foreign fraud and abuse laws and regulations, such as state anti- kickback and false claims laws, can apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors and are generally broad and are enforced by many different federal and state agencies as well as through private actions. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the EU Member States. Our failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Efforts to ensure that any business arrangements we have with third parties and our business generally will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse

or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm and the curtailment or restructuring of our operations. We are or may become subject to many cybersecurity, privacy and data protection laws in the U. S. and around the world. In the U. S., we are subject to numerous federal and state laws governing the collection, processing, use, transmission, disclosure, and sale (collectively, Processing) of personal data (which may also be referred to as personal information, personally identifiable information, and / or non- public personal information). **There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission (FTC) and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels.** For example, the **FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be " unfair " under Section 5 of the Federal Trade Commission Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The FTC is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC' s evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements. New laws also are being considered at the state level. For example, the California Consumer Privacy Act (** CCPA **)** went into effect on January 1, 2020, and established a new privacy framework for covered businesses such as ours. The CCPA imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA' s requirements are similar to those found in the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt- out of " sales " of their personal information. The CCPA contains significant penalties for companies that violate its requirements. Further, in November 2020, California voters passed the **California Privacy Rights Act (** CPRA **)** , which significantly expanded the CCPA to incorporate additional GDPR- like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. While certain of our business activities will not be subject to these laws, it remains unclear how various provisions of the CCPA and CPRA will be interpreted and enforced. In addition **to California** , **at least eleven** other states ~~, including Virginia, Colorado, Utah and Connecticut,~~ have passed **comprehensive** ~~similar state~~ privacy laws **similar to the CCPA and CPRA** . **These** ~~Virginia' s privacy law~~ **laws** ~~also went into~~ **are either in** effect **or** ~~on January 1, 2023, and the laws in the other three states~~ will go into effect ~~later in~~ **sometime before the end of 2026. Like the CCPA and CPRA,** ~~the~~ **these** ~~year~~ **laws create obligations related to the processing of personal information, as well as special obligations for the processing of " sensitive " data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2024 legislative sessions that will go into effect in 2024 and beyond, including New Hampshire and New Jersey** . Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. **There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data and additional states (including Vermont) are considering such legislation for 2024.** These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products ~~. These laws also may require us to incur additional costs and expenses in an effort to comply before the laws become effective on January 1, 2023. Recent laws such as the Biometric Information Privacy Act in Illinois have also restricted the use of biometric information. Such laws and regulations require us to continuously review our data processing practices and policies, may cause us to incur substantial costs with respect to compliance~~ . In addition, outside of the U. S., we are subject to foreign rules and regulations. Many countries outside of the U. S. maintain rigorous laws governing the privacy and security of personal information. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA, is subject to the GDPR, which became effective on May 25, 2018. This provision expanded the scope of data protection in the EU to foreign companies who process the personal data of EU residents, imposed a strict data protection compliance regime with stringent penalties for noncompliance and included new rights for data subjects such as the " portability " of personal data. In particular, under the GDPR, fines of up to € 20 million, or up to 4 % of

the annual global revenue of the noncompliant company, whichever is greater, could be imposed for violations of certain of the GDPR' s requirements. If we were found to be in breach of the GDPR, the potential penalties we might face could have a material adverse impact on our business, financial condition, results of operations, and cash flows. Compliance with the GDPR requires time and expense and may require us to make changes to our business operations. While the GDPR applies uniformly across the EU, each EU Member State is permitted to issue nation- specific data protection legislation, which has created inconsistencies on a country- by- country basis. Brexit has created further uncertainty and could result in the application of new data privacy and protection laws and standards to our operations in the U. K., our handling of personal data of users located in the U. K., and transfers of personal data between the EU and the U. K. Following the withdrawal of the U. K. from the EU, the U. K. Data Protection Act 2018 applies to the processing of personal data that takes place in the U. K. and includes parallel obligations to those set forth by GDPR. While the Data Protection Act of 2018 in the U. K. that " implements " and complements the GDPR has achieved Royal Assent on May 23, 2018, and is now effective in the U. K., it is still unclear whether **and for how long** transfer of data from the EEA to the U. K. will remain lawful under GDPR. The U. K. government has already determined that it considers all EU and EEA Member States to be adequate for the purposes of data protection, ensuring that data flows from the U. K. to the EU / EEA remain unaffected. In addition, a recent decision from the European Commission appears to deem the U. K. as being " essentially adequate " for purposes of data transfer from the EU to the U. K., although this decision may be re- evaluated in the future. There are ongoing concerns about the ability of companies to transfer personal data from the EU to other countries. On July 16, 2020, the European Court of Justice invalidated the EU- U. S. Privacy Shield Framework, a mechanism under which personal data could be transferred from the EEA to U. S. entities that had self-certified under the Privacy Shield Framework. The Court also called into question the Standard Contractual Clauses (SCCs), noting adequate safeguards must be met for SCCs to be valid. European regulatory guidance regarding these issues continues to evolve, and EU regulators across the EU Member States have taken different positions regarding continued data transfers to the U. S. In the future, SCCs and other data transfer mechanisms will face additional challenges. **In** ~~Additionally, in~~ October 2022, President Biden signed an executive order to implement the EU- U. S. Data Privacy Framework, which would serve as a replacement to the EU- U. S. Privacy Shield. The **EU** ~~European Commission~~ initiated the process to adopt an adequacy decision for the EU- U. S. Data Privacy Framework in December 2022 ~~. It is unclear if~~ and ~~when~~ the ~~framework~~ **European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision** will ~~be finalized and whether~~ **permit U. S. companies who self- certify to the EU- U. S. Data Privacy Framework to rely on** it **as a valid data transfer mechanism for data transfers from the EU to the U. S. However, some privacy advocacy groups have already suggested that they** will be **challenging the EU- U. S. Data Privacy Framework. If these** ~~challenged~~ **challenges** ~~in court~~ **are successful, they may not only impact the EU- U. S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms** . The uncertainty around this issue **has the potential to impact our business at the international level. Furthermore, while the Data Protection Act of 2018 in the U. K. that " implements " and complements the GDPR has achieved Royal Assent on May 23, 2018, and is now effective in the U. K., it is still unclear whether transfer of data from the EEA to the U. K. will remain lawful under the GDPR. The Agreement provides for a transitional period during which the U. K. will be treated like an EU member state in relation to processing and transfers of personal data for four months from January 1, 2021. This** may **be extended by two** further ~~impact our business operations~~ **months. After such period, the U. K. will be a " third country " under the GDPR unless the European Commission adopts an adequacy decision** in **respect of transfers of personal data to the U. K. The U. K. has already determined that it considers all of** the EU **and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the U. K. to the EU / EEA remain unaffected** . Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and any eventual sale and distribution of commercial products. Such laws may have potentially conflicting requirements or burdensome obligations that would make compliance challenging or expensive. Such changes may also require us to modify our products and features, and may limit our ability to make use of the data that we collect, may require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. Compliance with U. S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to Process data (including personal data), or in some cases, impact our ability to operate in certain jurisdictions. Any actual or alleged failure to comply with U. S. or international laws and regulations relating to privacy, data protection, and data security could result in governmental investigations, proceedings and enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to Process the information or impose other obligations or restrictions in connection with our Processing of information, and we may otherwise face contractual restrictions applicable to our Processing of information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, 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, suppliers and vendors may engage or may have engaged in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA, EMA or comparable foreign regulatory authority regulations, provide accurate

information to the FDA, EMA or comparable foreign regulatory authorities, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care 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. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct and engage contractors that agree to undertake certain measures with respect to their employees, but 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. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Our business activities may be subject to the FCPA and similar anti- bribery and anti- corruption laws of other countries in which we operate, as well as U. S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them. Our business activities may be subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third- party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition. In addition, our products may be subject to U. S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U. S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U. S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and / or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business. Risks related to employee matters, managing our growth and other risks related to our business Our success is highly dependent on our ability to attract, hire and retain highly skilled executive officers and employees. We currently have a small team focused on research and development of small molecule kinase inhibitors. To succeed, we must recruit, hire, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. **Personnel with the required skills and experience may be scarce or may not be available at all. In addition, competition for these skilled personnel is intense and recruiting and retaining skilled employees is difficult, particularly for a development- stage company such as ours. Even if we are successful in identifying, attracting, hiring and retaining qualified employees, recent market changes, including labor shortages, and rising inflation have increased employee-related costs substantially, which may negatively affect our operating results.** We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel **in** ~~, particularly at the~~ **these positions** ~~management level~~ , it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner ~~. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts~~ . Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be

more appealing to high- quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed. Additionally, we rely on our scientific founder and head scientific advisor, physician- scientist partners and other scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. Most of these advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non- compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting or employment relationships with our scientific founder and head scientific advisor, physician- scientist partners and other scientific and clinical advisors, or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed. For example, if we are no longer able to access our network of physician- scientists, our ability to define and characterize patients' needs for future product candidate development may be negatively affected. Our reliance on a limited number of employees who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business. As of December 31, ~~2022~~ **2023**, we had ~~62~~ **92** full- time employees, upon which we rely for various administrative, research and development, and other services. The small size of our centralized team may limit our ability to devote adequate personnel, time, and resources to support our operations or research and development activities, and the management of financial, accounting, and reporting matters. If our team fails to provide adequate administrative, research and development, or other services across our organization, our business, financial condition, and results of operations could be harmed. We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth. As of December 31, ~~2022~~ **2023**, we had ~~62~~ **92** full- time employees, including ~~46~~ **66** employees engaged in research and development activities. In order to successfully implement our development and commercialization plans and strategies, and as we continue to grow as a public company, we expect to need significant additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining, retaining and motivating our current and additional employees; • managing our internal development efforts effectively, including the preclinical, clinical, FDA, EMA and other comparable foreign regulatory authorities' review process for NVL- 520, NVL- 655, NVL- 330 and our discovery programs, while complying with any contractual obligations to contractors and other third parties; • managing increasing operational and managerial complexity; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to successfully develop and, if approved, commercialize NVL- 520, NVL- 655, NVL- 330 and any future product candidates developed from our discovery programs and other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of research, clinical development and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third- party service providers is compromised for any reason, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval for any of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing third- party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and / or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize NVL- 520, NVL- 655, NVL- 330 or any future product candidate from our discovery programs and any of our other product candidates and, accordingly, may not achieve our research, development and commercialization goals. Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer actual or suspected 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, and potentially significant delays in our delivery to market. Despite the implementation of security measures in an effort to protect systems that store our data, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and external processing and storage systems (i. e., cloud), and those of our third- party CROs, other contractors (including sites performing our clinical trials) and consultants, 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 (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. **The risk of a security breach or disruption through cyber- attacks has generally increased as the number, intensity and sophistication of attempted attacks from around the world have increased.** For example, companies have experienced an increase in phishing

and social engineering attacks from third parties. Also, a majority of our employees are working remotely. As a result, we may have increased ~~cyber security~~ **cybersecurity** and data security risks, due to increased use of home wi- fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement IT controls to reduce the risk of a ~~cyber security~~ **cybersecurity** or data security breach, there is no guarantee that these measures will be adequate to safeguard all systems. 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 (including confidential information and personal data) or applications, 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 our product candidates could be delayed. There can be no assurance that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data, as well as claims or investigations from regulators or other third parties. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and / or unauthorized access, use, or disclosure of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal data), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal data, including personal data regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to financial exposure related to investigation of the incident (including cost of forensic examinations), subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. Notifications, follow- up actions, claims and investigations related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach. We also rely on third parties to manufacture our product candidates, 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 incident were to result in a loss, destruction or alteration of, or damage to, our data (including personal data), or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and / or privacy and security laws from countries outside of the U. S. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption 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. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Many of our research, manufacturing and preclinical activities are conducted by third parties outside of the U. S., including without limitation in China and India. A significant disruption in the operations of those third parties, a war, a trade war or political unrest could materially adversely affect our business, financial condition and results of operations. We contract many of our research, manufacturing and preclinical activities to third parties outside the U. S., including without limitation, in China and India. Any disruption in the operations of such third parties or in their ability to meet our needs, whether as a result of a natural disaster, war or other causes, could impair our ability to operate our business on a day- to- day basis and to continue development of our programs. Furthermore, since many of these third parties are located outside the U. S., we are exposed to the possibility of disruption and increased costs in the event of changes in the policies of the U. S. or foreign governments, war, political unrest or unstable economic conditions in any of the countries where we conduct such activities. For example, a war or trade war could lead to tariffs, embargoes, sanctions or other limitations on trade, including without limitation those placed on Russia as a result of its military conflict with Ukraine, that may affect our ability to source the chemical intermediates used in our product candidates. By way of further example, a natural disaster, war, civil or political unrest or similar circumstances could hinder our ability to maintain or initiate clinical studies at our preferred sites, causing trial initiation or implementation delays. Any of these matters could materially and adversely affect our development timelines, business and financial condition. Our operations are vulnerable to interruption by flood, fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business. Our corporate headquarters are located in Cambridge, Massachusetts. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, fire, earthquake, power loss, telecommunications failure, terrorist activity, pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. **Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information and personal data. Issues in the use of**

artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If any of our vendors experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business. If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval. We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks. Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time- consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory- by- territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to enter into such arrangements when needed, on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses. A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business. We may seek regulatory approval of our product candidates outside of the U. S. and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including: • differing regulatory requirements and reimbursement regimes in foreign countries, such as the lack of pathways for accelerated drug approval, may result in foreign regulatory approvals taking longer and being more costly than obtaining approval in the U. S.; • foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from preclinical studies or clinical trials; • approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; • impact of pandemics **or other public health emergencies, natural disasters** and ~~global~~ geopolitical events on our ability to produce our product candidates and conduct clinical trials in foreign countries; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with legal requirements applicable to privacy, data protection, information security and other matters; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • difficulties staffing and managing foreign operations; • complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries; • workforce uncertainty in countries where labor unrest is more common than in the U. S.; • potential liability under the FCPA or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U. S.; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical ~~actions~~ **events** , including war and terrorism, trade policies, treaties and tariffs. These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations. Changes in tax law could adversely affect our business and 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, the U. S. Treasury Department and other applicable tax authorities. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited. Our federal net operating loss (NOL) carryforwards may be unavailable to offset future taxable income because of restrictions under U. S. tax law. Under tax legislation commonly referred to as the Tax Act **,** as amended by the **CARES** ~~Coronavirus Aid, Relief, and Economic Security~~ Act, our federal NOLs may be carried forward indefinitely, but for taxable years beginning after December

31, 2020, the deductibility of federal NOL carryforwards generated in tax years beginning after December 31, 2017 is limited to 80 % of our current year taxable income. ~~It is uncertain if and to what extent various states will conform to the Tax Act.~~ As of December 31, ~~2022~~ **2023**, we had available federal NOL carryforwards of approximately $ ~~91~~ **123**. ~~1~~ **7** million and available state NOL carryforwards of approximately $ ~~90~~ **144**. ~~5~~ **0** million ~~, which begin to expire in 2037~~. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an " ownership change " (generally defined as a cumulative change in the corporation' s ownership by " 5- percent shareholders " that exceeds 50 percentage points (by value) over a rolling three- year period), the corporation' s ability to use its pre- change NOL carryforwards and certain other pre- change tax attributes to offset its post- change taxable income may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. There is also a risk that due to regulatory changes, such as suspensions on the use of NOL carryforwards, or other unforeseen reasons, our existing NOL carryforwards could expire or otherwise be unavailable to offset future income tax liabilities. Because our ability to utilize our NOL carryforwards and certain other tax attributes could be limited as described above, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations. Risks related to our intellectual property Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party. Derivation proceedings provoked by third parties or brought by us or declared by the U. S. Patent and Trademark Office (USPTO) may be necessary to determine the priority of inventions with respect to one or more of our patents or patent applications or those of our future licensors. An unfavorable outcome may require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be adversely affected if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our development programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market. If we are unable to obtain, maintain and enforce patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected. Our success depends in large part on our ability to obtain and maintain protection of the intellectual property rights we own (either solely and jointly with others), or may in the future license from third parties (in particular, worldwide patents relating to any proprietary technology and product candidates we develop). We seek to protect our proprietary position by filing patent applications in the U. S. and select other countries related to our technologies and product candidates that are important to our business and by in- licensing intellectual property related to such technologies and product candidates. We do not yet have issued patents for all of our most advanced product candidates in all markets in which we may commercialize them, but we continue to actively pursue patent protection for our technology and product candidates in certain jurisdictions around the world. However, we cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, or the methods of use or manufacture of those products. If we are unable to obtain and maintain meaningful patent protection in jurisdictions important to our business for our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, or other proprietary technologies our business, financial condition, results of operations and prospects could be adversely affected. The patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain or defend all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances involving technology that we may license from third parties, we may not have the sole right to control the preparation, filing and prosecution of patent applications or to maintain, enforce and defend the in- licensed patents. Therefore, any in- licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business. The patent rights of pharmaceutical and biotechnology companies, like ours, generally are highly uncertain, involve complex legal and factual questions and have been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents, particularly those related to oncology, has emerged in the U. S. The relevant patent laws and their interpretation outside of the U. S. are also uncertain. Various courts, including the U. S. Supreme Court, have rendered decisions that affect the scope of patent eligibility of certain inventions or discoveries relating to biotechnology. These decisions conclude, among other things, that abstract ideas, natural phenomena and laws of nature are not themselves patent eligible subject matter. Precisely what constitutes a law of nature or abstract idea is uncertain, and certain aspects of our technology could be considered ineligible for patenting under applicable law. In addition, the scope of patent protection outside the U. S. is uncertain, and laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. or vice versa. For example, European patent law precludes the patentability of methods of treatment of the human body. We cannot predict whether the patent applications we are currently pursuing will issue as patents that protect our technology and product candidates, in whole or in part, in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Changes in either the patent laws or interpretation of the patent laws in the U. S. or other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce

our patent rights, narrow the scope of our patent protection and, more generally, affect the value or narrow the scope of our patent rights. Further, third parties may have intellectual property rights relating to our product candidates of which we are unaware. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published at all. Therefore, neither we nor our future licensors can know with certainty whether either we or our future licensors were the first to make the inventions claimed in the patent applications we own or any patents or patent applications we may own or in- license in the future, or that either we or any of our future licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and future in- licensed patent rights are uncertain. For example, currently unpublished patent applications may later publish and limit our ability to obtain valid and enforceable patents. Moreover, any issued patents we do obtain or in- license may be challenged, invalidated, or circumvented. We or our future licensors may be subject to a third- party pre- issuance submission of prior art to the USPTO, or to a foreign patent office, or become involved in opposition, derivation, revocation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third- party patent rights. If the breadth or strength of protection provided by any patents we obtain and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Moreover, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents we may obtain. For these reasons and others, we may face competition with respect to our product candidates. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and any future in- licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and any patents we do obtain may be challenged in the courts or patent offices in the U. S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Furthermore, our competitors may be able to circumvent any patents we obtain or in- license in the future by developing similar or alternative technologies or products in a non- infringing manner. For these reasons, even if we are successful in obtaining patents or in- licensing patents in the future, our patent portfolio may not provide us with sufficient rights to exclude others from using or commercializing technology and products similar or identical to any of our technology and product candidates for any period of time. Patent terms may not protect our competitive position for an adequate amount of time. Issued patents can provide protection for varying periods of time, depending, for example, upon the type of patent, the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. However, patents have a limited lifespan. In the U. S., 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. The term of a patent outside of the U. S. varies in accordance with the laws of the foreign jurisdiction. 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. 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 approved for use or commercialized. If we do not obtain patent term extension in the U. S. under the Hatch- Waxman Act and in foreign countries under similar legislation, which if granted could extend the term of our marketing exclusivity for any product candidates we may develop, our business may be materially and adversely affected. In the U. S., the term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, permits a patent term extension of up to five years beyond the expiration date of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. In addition, the patent term of only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non- U. S. jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on any patents that issue covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted and, even if granted, the length of such extensions. We may not be granted patent term extension either in the U. S. or in any foreign country, even where we obtain a patent that is eligible for patent term extension, if, for example, an applicable government authority determines that we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we obtain such

an extension, it may be for a shorter period than we had sought. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially and adversely affected. Furthermore, for any patents we may in- license in the future, we may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch- Waxman Act. Thus, if a patent we in- license in the future is eligible for patent term extension under the Hatch- Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed or whether the requested extension is obtained from the USPTO. Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain or in- license patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we or our future licensors submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate. Changes to patent laws in the U. S. 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 U. S. or other jurisdictions 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 any issued patents we may obtain or in- license. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. For example, the USPTO regularly revises its policies and procedures for patent examination. Future political changes may impose new difficulties in obtaining patent protection. This combination of events has increased uncertainty with respect to the validity and enforceability of patents once obtained. Similarly, foreign courts and patent offices have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U. S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain patent protection in the future. We may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Competitors and other third parties may infringe, misappropriate or otherwise violate patents or other intellectual property that we own or license. As a result, we or our future licensors may need to file infringement, misappropriation or other intellectual property claims, which can be expensive and time- consuming. Any claims we assert against others could provoke them to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on in the extent to which we obtain and enforce patent claims that cover our technology, inventions, and improvements. Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. In a patent infringement proceeding, the perceived infringers could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the U. S., defendant counterclaims alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non- enablement. Grounds for an unenforceability assertion include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the U. S. or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings in the European Patent Office. The outcomes of allegations of invalidity or unenforceability are unpredictable. With respect to validity, for example, even if we are successful in obtaining patents or in- licensing patents, we cannot be certain that there is no invalidating prior art of which the patent examiner and we or our future licensing partners were unaware during prosecution. An adverse result in any such proceeding could put one or more of the patents that we may own or in- license in the future at risk of being invalidated or interpreted narrowly, and could put any of our present or future owned or in- licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third party from using the technology at issue in a proceeding, for example, on the basis that our owned or in- licensed patents do not cover that technology. Furthermore, if the breadth or strength of protection provided by our patent applications and any future patents is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products, diagnostic tests or services. In addition, interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patent applications or any future patents. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be adversely affected if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non- exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our discovery programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. 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 or trade secrets could be compromised by disclosure during litigation. Any of the foregoing could allow third parties to develop and commercialize competing technologies and products and have a material

adverse impact on our business, financial condition, results of operations and prospects. Third parties may allege that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business. Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, inter partes review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates may be subject to claims that they infringe the patent rights of third parties. Our competitors and others may have significantly larger and more mature patent portfolios than we have. In addition, future litigation may be initiated by patent holding companies or other third parties who have no relevant product or service revenue and against whom our future patents, if any, may provide little or no deterrence or protection. Competitors may also assert that our product candidates infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources and management attention to defend. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. Because patent applications can take many years to issue, pending patent applications may result in issued patents that our product candidates infringe. For example, there may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the discovery, use or manufacture of our product candidates or technologies. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates, or we may incorrectly conclude that third- party intellectual property is invalid or that our activities and product candidates do not infringe the intellectual property rights of third parties. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party' s intellectual property rights. Parties making claims against us may also obtain injunctive or other equitable relief. For example, if any third- party patents were held to cover the manufacturing process of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidates. In the event of a successful claim of infringement against us, we may also have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, indemnify customers, collaborators or other third parties, seek new regulatory approvals, and redesign our infringing products, which may not be possible or practical. If we are found to infringe, misappropriate or otherwise violate a third party' s intellectual property rights, we may be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and could require us to make substantial licensing and royalty payments. Claims that we have misappropriated the confidential information, trade secrets or other intellectual property rights of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects. If we are unable to obtain licenses from third parties on commercially reasonable terms, our business could be adversely affected. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from the third parties. The in- licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to in- 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, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to sell, assign or license rights to us. In addition, we expect that competition for the in- licensing or acquisition of third- party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, such as substantial licensing or royalty payments, our business could be materially and adversely affected. If we are unable to obtain a necessary license, the third parties owning such intellectual property rights could seek an injunction prohibiting our sales or we may be unable to otherwise develop or commercialize the affected product candidates, which could materially harm our business. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to obtain rights to required third- party intellectual property rights, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them 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 technology and product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. If we fail to comply with our obligations in any future intellectual property licenses with third parties that we may enter into, or otherwise experience disruptions to our business relationships with our future licensors, we could lose intellectual property rights that are important to our business. We may in the future enter into licensing and funding arrangements with third parties

that may impose, among other things, diligence, development, and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with those obligations, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements, or our counterparties may require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects, or impede, delay or prohibit the further development or commercialization of, one or more product candidates that rely on such agreements. For example, disputes may arise regarding intellectual property that is or becomes subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other matters of contract interpretation; • whether and the extent to which our technology and processes infringe the intellectual property rights of the licensor that are not subject to the licensing agreement; • whether our licensor or its licensor had the right to grant the license agreement; • whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization; • our involvement in the prosecution of licensed patents and our licensors' overall patent enforcement strategy; • the amounts of royalties, milestones or other payments due under the license agreement; • the sublicensing of patent and other rights under collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • the priority of invention of patented technology. • If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements. In addition, intellectual property license agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Our future licensors may rely on third- party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we may in- license. If other third parties have ownership rights to patents and / or patent applications we may in- license, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our in- licensed patents in order to enforce such patents against third parties, and we may not receive such cooperation. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Despite our efforts, our future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in- licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors could seek regulatory approval for and market products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. We may not be able to protect our intellectual property and proprietary rights throughout the world. Third parties may attempt to develop and commercialize competitive products in foreign countries where we do not have any patent protection and / or where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations. Filing, prosecuting, and defending patents on product candidates in all countries 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 U. S., and even where such protection is nominally available, adequate judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling our inventions in such countries or importing products made using our inventions into the U. S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we do obtain patent protection or future licenses but enforcement is not as strong as that in the U. S. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop the infringement of any patents we do obtain or in- license or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect, to the same extent as the U. S. or at all, inventions that constitute new methods of treatment. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we obtain at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits

that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We work with third- party contractors located in China to develop certain of our intellectual property. On December 1, 2020, the Chinese government implemented a new Export Control Law which regulates the export of certain technologies outside of China. As currently implemented, we do not believe the Export Control Law applies to our product candidates, and we do not expect it to impact our business; however the Export Control Law could be amended in the future in a way that could adversely affect our business. Many countries, including India, China and certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we do obtain or in- license patents and we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations, and prospects may be adversely affected. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We or our future licensors may be subject to claims that current or former employees, collaborators, CROs, universities or other third parties have an interest in our owned or future in- licensed patents and patent applications, trade secrets or other intellectual property as an inventor, co- inventor, owner or co- owner. For example, we or our future licensors may have inventorship or ownership disputes **that** arise from conflicting obligations of employees, consultants, CROs or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of any future owned or in- licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, we may be required to pay monetary damages and we may also lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. 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. Additionally, if residents of other countries can claim inventorship of our patents and patent applications, we may be required to fulfill additional obligations. For example, some countries, including China, require a patent owner to provide remuneration to inventors who assign rights to inventions developed during course of their employment. Litigation may be necessary to defend against claims based on foreign inventors. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Intellectual property discovered through government funded programs may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- U. S. manufacturers. We may in the future develop, acquire, or license intellectual property rights that have been generated through the use of U. S. government funding or grants. Pursuant to the Bayh- Dole Act of 1980, the U. S. government has certain rights in inventions developed with government funding. These U. S. government rights 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, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). If the U. S. government exercises its " march- in " rights in any future intellectual property rights that are generated through the use of U. S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we may license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U. S. government for the exercise of such rights. The U. S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U. S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the U. S. This preference for U. S. industry may be waived by the federal agency that provided the funding if the owner or assignee 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 U. S. or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. industry may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects. We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of such third parties, or that they have wrongfully used or disclosed alleged trade secrets of their current or former employers, or that we have misappropriated their intellectual property, or that they own what we regard as our own intellectual property. Many of our employees, physician- scientist partners, consultants and contractors are or were previously employed at or engaged by universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Many of them executed proprietary rights, non- disclosure and / or non- competition agreements in connection with such previous employment or engagement. Although we try to ensure that the individuals who work for us do not use the intellectual property rights, proprietary information, know- how or trade secrets of others in their work for us, we may be subject to claims that we or they have, inadvertently or otherwise, used, infringed, misappropriated or otherwise violated the intellectual property rights, or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties. We may also be subject to claims that we have improperly used or obtained such trade secrets. Litigation may

be necessary to defend against these claims. Any litigation or the threat of litigation may adversely affect our ability to hire employees or engage consultants and contractors. A loss of key personnel or their work product could hamper or prevent us from developing and commercializing products and product candidates, which could harm our business. In addition, while it is our policy to require our employees, physician- scientist partners, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining such an agreement from each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Additionally, assignment agreements and related agreements may be interpreted under the laws of a foreign country, which may be unpredictable. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. If we fail in prosecuting or defending any such claims, we may be required to pay monetary damages, and we may also lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive position and prospects. 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, which license may not be available on commercially reasonable terms, or at all, or such license may be non- exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees. If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position would be adversely affected. In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know- how, technology and other proprietary information to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, our unpublished patent applications or other confidential research, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U. S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us. Furthermore, we expect that, over time, our trade secrets, know- how and proprietary information may be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel to and from academic and industry scientific positions. Consequently, without costly efforts to protect our proprietary technology, we may be unable to prevent others from exploiting that technology, which could affect our ability to expand in domestic and international markets. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely affected. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. These security measures may be breached or otherwise accessed in an unauthorized manner, and we may not have adequate remedies for any breach. If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition or cancellation proceedings. This can be time- consuming and expensive, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may determine another trademark is not infringing our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these trademarks or trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trademarks or trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark or trade name infringement claims brought by owners of other registered trademarks or trade names that incorporate variations of our trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks and trade names may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. Our current trademark applications and additional trademark applications we may file in the future may not proceed to registration and / or may be opposed by third parties. Even if such applications proceed to registration, third parties may challenge our use of such trademarks or seek to invalidate our registration in the future. Other companies in our industry may be using trademarks that are similar to ours and may in the future allege that the use of our trademarks in connection with our products infringes or otherwise violates their trademark rights. Trademark- granting authorities may decide to investigate our trademarks on their own initiative if they believe that there may be potential issues to be resolved. In addition, failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect and enforce our trademarks and impede our

marketing efforts in the countries in which we operate. Over the long term, if we are unable to establish brand recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Risks related to our dependence on third parties We rely on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies. We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners (collectively, partners) to conduct and support our preclinical studies and our clinical trials under agreements with us and plan to continue to do so for our future **preclinical studies and** clinical trials. These third parties have had and will continue to have a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. For example, our partners contribute highly enabling technologies and services that include: (i) numerous physician- scientists at leading CROs, (ii) support for our translational research efforts, (iii) crystallography to enable structure- based drug discovery, (iv) biochemical and cell- based assays to guide lead generation and optimization, and (v) patient- derived, cell and xenograft models to translate our findings to the clinical setting. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our preclinical studies or our clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. Some of these third parties may terminate their engagements with us at any time. We also ~~expect to~~ have to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines. Our heavy reliance on these third parties for such drug development activities ~~will reduce~~ **reduces** our control over these activities. As a result, we ~~will~~ have less direct control over the conduct, timing and completion of preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we ~~will~~ remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, 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. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations and ~~will~~ require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials, and expect to continue to do so for additional preclinical studies, clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quality and quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third- party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long- term supply agreements, and we enter into contracts for the production of our product candidates on an as- needed basis, which means that aside from any binding purchase orders we have from time to time, we are subject to the supplier' s plant availability, ability to manufacture on our behalf, and / or a change in the terms on which it is willing to continue supplying to us at any time. If we were to experience an unexpected loss of supply of any of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing preclinical studies or clinical trials. We expect to continue to rely on third- party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third- party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • the failure of the third party to manufacture our product candidates according

to our schedule and specifications, or at all, including if our third- party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them; • the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms; • the termination or nonrenewal of arrangements or agreements by our third- party contractors at a time that is costly or inconvenient for us; • the breach by the third- party contractors of our agreements with them; • the failure of the third party to manufacture our product candidates according to our specifications; • the failure of third- party contractors to comply with applicable regulatory requirements, including cGMPs; • the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified; • clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and • the misappropriation of our proprietary information, including our trade secrets and know- how. We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for general project management, in- person oversight and for compliance with cGMP regulations for manufacturing both API and finished drug products. To date, we have obtained API and drug product for our product candidates from a limited group of third party contract manufacturers, and we continue to develop our supply chain for each of our product candidates. As we advance our product candidates through development, we will continue to take steps to protect against any potential supply disruptions through the use of a safety stock strategy and by maintaining relationships and contracting with additional suppliers. However, we may be unsuccessful in maintaining or putting in place additional framework agreements or protecting against potential supply disruptions. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the U. S. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities, they will not be able to secure and / or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by the FDA, EMA or a comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. If any third- party manufacturer with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different third- party manufacturer, which we may not be able to do on reasonable terms, if at all. As a result, our clinical trial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original third- party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new third- party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new third- party manufacturer could negatively affect our ability to develop product candidates or commercialize our anticipated products in a timely manner or within budget. Furthermore, a third- party manufacturer may possess technology related to the manufacture of our product candidate that such third- party manufacturer owns independently. This would increase our reliance on such third- party manufacturer or require us to obtain a license from them in order to have another third- party manufacturer manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals. In order to commercially produce our products either at a third party' s facility or in any facility of ours, we will need to comply with the FDA' s cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non- compliance could also result in the imposition of sanctions,

including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business. If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, product candidates, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: • increased operating expenses and cash requirements; • the assumption of additional indebtedness or contingent liabilities; • the issuance of our equity securities; • assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel; • the diversion of our management' s attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition; • retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products, product candidates and marketing approvals; and • our inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. If our third- party manufacturers use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third- party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U. S. and local laws in other foreign jurisdictions governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, federal or foreign authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. If we decide to establish collaborations, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans. Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. We face significant competition in seeking appropriate collaborators and the negotiation process is time- consuming and complex. Whether we reach a definitive agreement for a collaboration depends, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of preclinical studies or clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators. If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our discovery programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. If we enter into any collaboration arrangements with any third parties for the development and commercialization of our product candidates, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities and efforts to

successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected; • collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products; • we may grant exclusive rights to our collaborators that would prevent us from collaborating with others; • collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings; • 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; • 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; • collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; • collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates; • collaborators may own or co- own intellectual property covering our products or product candidates that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and • a collaborator' s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings. Risks related to ownership of our common stock The market price of our Class A common stock may be volatile, and our investors could lose all or part of their investment. The trading price of our Class A common stock **has been and** is likely to **continue to** be highly volatile and subject to wide fluctuations in response to various factors, ~~some~~ **many** of which we cannot control. 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 Class A common stock, regardless of our actual operating performance. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report, these factors include **, without limitation** : • the timing and results of INDs, preclinical studies and clinical trials of our product candidates or those of our competitors; • the success of competitive products or announcements by potential competitors of their product development efforts; • regulatory actions with respect to our products or product candidates or our competitors' products or product candidates; • actual or anticipated changes in our growth rate relative to our competitors; • regulatory or legal developments in the U. S. and other countries; • developments or disputes concerning our patent applications, issued patents, or other proprietary rights; • the recruitment or departure of key personnel; • announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • market conditions in the pharmaceutical and biotechnology sector; • changes in the structure of healthcare payment systems; • 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; • expiration of market stand- off or lock- up agreements; • the impact of any ~~natural disasters,~~ public health emergencies, **natural disasters, or** ~~such as the ongoing COVID- 19 pandemic and other global~~ geopolitical events, ~~such as the ongoing~~ **including civil or political unrest or** military ~~conflict~~ **conflicts** ~~between Russia and Ukraine~~ ; and • general economic, political, industry and market conditions. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and adverse impact on the market price of our Class A common stock. If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline. The trading market for our Class A common stock may be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance. Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments

and / or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock- based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee' s requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following: • the timing and cost of, and level of investment in, research and development activities relating to our programs, which will change from time to time; • our ability to enroll patients in clinical trials and the timing of enrollment; • the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers; • expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets; • the timing and outcomes of preclinical studies and clinical trials for NVL- 520, NVL- 655, NVL- 330 and any product candidates from our discovery programs, or competing product candidates; • the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated; • competition from existing and potential future products that compete with NVL- 520, NVL- 655, NVL- 330 or any of our discovery programs, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners; • any delays in regulatory review or approval of NVL- 520, NVL- 655, NVL- 330 or product candidates from any of our discovery programs; • the level of demand for any of our product candidates, if approved, which may fluctuate significantly and be difficult to predict; • the risk / benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with NVL- 520, NVL- 655, NVL- 330 or any of our discovery programs; • our ability to commercialize NVL- 520, NVL- 655, NVL- 330 or product candidates from any of our discovery programs, if approved, inside and outside of the U. S., either independently or working with third parties; • our ability to establish and maintain collaborations, licensing or other arrangements; • our ability to adequately support future growth; • potential unforeseen business disruptions that increase our costs or expenses; • future accounting pronouncements or changes in our accounting policies; and • the changing, volatile and instable global economic and political environment. The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our Class A common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. Global credit and financial markets have experienced extreme instability, volatility and disruptions in the past several years due to **a number of factors, including** the ~~ongoing~~ COVID- 19 pandemic, ~~events around the~~ ongoing military ~~conflict~~ **conflicts** ~~between Russia and Ukraine~~ , **bank failures** and other market- influencing developments, including severely diminished liquidity and credit availability, declines in consumer confidence, **increases in interest rates,** declines in economic growth, increases in unemployment rates, increases in inflation and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions, whether due to **public health emergencies** ~~the evolving effects of the COVID- 19 pandemic~~ , ~~the~~ military ~~conflict~~ **conflicts , bank failures** ~~between Russia and Ukraine~~ or otherwise, will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure additional financing in a timely manner and on favorable terms could have a material adverse ~~event~~ **effect** on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Our stock price may decline due in part to the volatility of the stock market and the general economic downturn. Our principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Three of our directors are affiliated with two of our principal stockholders. Our holders of 5 % or more of our capital stock and their respective affiliates beneficially own in excess of 50 % of our outstanding Class A common stock and Class B common stock and in excess of 50 % of our Class A voting stock. Three of our directors are affiliated with two of our principal stockholders **:** ~~, including~~ Joseph Pearlberg, M. D., Ph. D. and Cameron A. Wheeler, Ph. D. ~~who~~ are affiliated with Deerfield, and Andrew A. F. Hack, M. D., Ph. D. ~~who~~ is affiliated with Bain Capital Life Sciences. These stockholders, acting together or on their own, may be able to impact matters requiring stockholder approval. For example, they may be able to impact 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 investors may feel are in their best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with each investor' s 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 Class A common stock. The dual class structure of our common stock and the option of the holders of shares of our Class B common

stock to convert into shares of our Class A common stock may limit our Class A common stockholders' ability to influence corporate matters. Our Class A common stock has one vote per share, while our Class B common stock is non- voting. Nonetheless, each share of our Class B common stock may be converted at any time into one share of Class A common stock at the option of its holder, subject to the limitations provided for in our third amended and restated certificate of incorporation **, as amended,** that prohibit the conversion of our Class B common stock into shares of Class A common stock to the extent that, upon such conversion, such holder and any other persons with whom such holder' s beneficial ownership would be aggregated for purposes of Section 13 (d) of the Exchange Act would beneficially own in excess of 4. 9 % or 9. 9 %, as applicable, based on the holder' s election of any class of our securities registered under the Exchange Act. Consequently, if holders of Class B common stock exercise their option to make this conversion, such exercise will have the effect of increasing the relative voting power of those prior holders of our Class B common stock (subject to the ownership limitation described in the previous sentence) and increasing the number of outstanding shares of our voting common stock, and correspondingly decreasing the relative voting power of the current holders of our Class A common stock, which may limit our Class A common stockholders' ability to influence corporate matters. Because our Class B common stock is generally non- voting, stockholders who own more than 10 % of our common stock overall but 10 % or less of our Class A common stock will not be required to report changes in their ownership from transactions in our common stock pursuant to Section 16 (a) of the Exchange Act and would not be subject to the short- swing profit provisions of Section 16 (b) of the Exchange Act. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2021 Stock Option and Incentive Plan (2021 Plan), could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall. ~~We expect that additional~~ **Additional** capital ~~may~~ **will** be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by such sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock. Pursuant to our 2021 Plan, our management is authorized to grant stock options to our employees, directors and consultants. If the number of shares reserved under our 2021 Plan is increased pursuant to the terms of our 2021 Plan, our stockholders may experience dilution, which could cause our stock price to fall. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. For example, ~~on November 3,~~ **in the fourth quarter of** ~~2022~~ **2023** , we issued and sold ~~7~~ **6** , ~~895~~ **160** , ~~522~~ **714** shares of Class A common stock in a follow- on public offering. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through future strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us. We are **no longer** an " emerging growth company " and **will soon be unable to take advantage of the scaled disclosure requirements available to** a **"** smaller reporting company **"** , and ~~we cannot be certain if~~ the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will **therefore no longer apply** ~~make our common stock less attractive~~ to ~~investors~~ **us** . ~~We~~ **Due to our public float as of June 30, 2023, we became a "** ~~are~~ **large accelerated filer " as of December 31, 2023 and no longer qualify as** an " emerging growth company ~~,~~ " **,** as defined in the JOBS Act. ~~For~~ **In addition, due to our public float** as **of June 30, 2023, we will be unable to take advantage of the scaled public disclosure requirements available to " smaller reporting companies ", beginning with the filing of our quarterly report on Form 10- Q for the three- month period ending March 31, 2024. As a large accelerated filer, and because we no** ~~long~~ **longer qualify** as ~~we continue to be~~ an emerging growth company ~~, we intend~~ **and will soon be unable** to take advantage of ~~exemptions from various~~ **the scaled disclosures available to smaller** reporting **companies, we are subject to certain additional disclosure** requirements **applicable to other large accelerated filers and** that ~~are~~ **were not** applicable to **us in the past, which will increase our legal, accounting and** other **expenses. These additional requirements** ~~public companies that are not emerging growth companies, including~~ **include , among other things** : • ~~being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure in our periodic reports; • not~~ being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended (the Sarbanes- Oxley Act); • ~~not~~ being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; • ~~reduced~~ **additional** disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and • ~~exemptions from~~ the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. ~~Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until~~ **Until** ~~such time as~~ **our quarterly report on Form 10- Q for** ~~those~~ -- **the** ~~standards apply~~ **three- month period ending March 31, 2024, we intend** to **take advantage** ~~private companies. We have elected to avail~~

~~ourselves~~ of ~~this exemption~~ **exemptions** from **various reporting requirements that are applicable** ~~new or revised accounting standards and, therefore, will not be subject~~ to ~~the same new or revised accounting standards as~~ other public companies that are not ~~emerging growth~~ **smaller reporting** companies ~~. As a result~~ , ~~our~~ **including: • being permitted to provide only two years of audited** financial statements **, in addition** ~~may not be comparable~~ to ~~companies that comply~~ **any required unaudited interim financial statements,** with **correspondingly reduced " Management' s Discussion** ~~the new or revised accounting pronouncements as of public company effective dates. We will remain an~~ **and** ~~emerging growth company until the earliest to~~ **Analysis of Financial Condition and Results of Operations " disclosure in** ~~occur~~ -- **our periodic reports** ~~of: (i) the last day of the fiscal year in which we have more than $ 1. 07 billion in annual revenue~~ ; ~~(ii) the date we qualify as a " large accelerated filer, " with at least $ 700. 0 million of equity securities held by non- affiliates; (iii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt securities during the prior three- year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our IPO. Even after we no longer qualify as an~~ **and •** ~~emerging growth company, we may still qualify as a " smaller reporting company, " which would allow us to continue to take advantage of many of the same 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 **that are similar to those available for emerging growth companies** . **These scaled disclosures** ~~We cannot predict if investors~~ will ~~find~~ **no longer be applicable** ~~our~~ **or available to us beginning with our quarterly report** ~~Class A common stock less attractive because we may rely~~ on **Form 10- Q for the** ~~these~~ **three** ~~exemptions~~ **- month period ending March 31, 2024** . We have increased costs as a result of operating as a public company, and our management is devoting substantial time to related compliance initiatives. As a public company, we are incurring significant legal, accounting and other expenses, and these expenses ~~may~~ **are likely to** increase ~~even~~ **further due to our transition out of " emerging growth company " and " smaller reporting company " status. We are and will continue to be subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act, and the Dodd- Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including those related to climate change and other environmental, social and governance focused disclosures, are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities** more ~~after coverage~~ **time consuming** . ~~We~~ **Our management and other personnel need to devote a substantial amount of time to these compliance initiatives and we** cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements ~~. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers~~ . In addition, as a public company we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes- Oxley Act. Under these rules, we are required to **maintain effective disclosure and financial controls and to** make a formal assessment of the effectiveness of our internal control over **financial reporting. In addition, now that** we are no longer an " emerging growth company ~~.~~ **,** " **we are** ~~We will be~~ subject to ~~the reporting requirements~~ **Section 404 (b)** of ~~the Exchange Act,~~ the Sarbanes- Oxley Act, ~~and the Dodd- Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time- consuming and costly,~~ which **requires** ~~will increase our operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for~~ us to obtain director and officer liability insurance..... growth company, we may be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. ~~To achieve compliance~~ **Compliance** with Section 404 **has been and** ~~within the prescribed period, we~~ will **continue** ~~be engaging in a process~~ to **be** ~~document and evaluate our internal control over financial reporting, which is~~ both costly and **time- consuming** ~~challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process~~ for **our management** ~~internal control over financial reporting~~ . If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock. We may in the future discover material 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. ~~We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2022, in accordance with the provisions of the Sarbanes- Oxley Act.~~ Accordingly, we cannot assure our stockholders that we will not in the future identify material weaknesses. ~~Material weaknesses may exist when we become required to report on the effectiveness of our internal control over financial reporting under Section 404 of the Sarbanes- Oxley Act.~~ If we **have** ~~are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in~~ a ~~timely manner,~~ **material weakness in** ~~or~~ **our** ~~if we are unable to maintain proper and effective~~ internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to

sanctions or investigations by the stock exchange on which our Class A common stock is listed, the SEC or other regulatory authorities. 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. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and 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 facts 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 due to error or fraud may occur and not be detected. We may be subject to securities litigation, which is expensive and could divert management attention. The market price of our Class A common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock. Anti- takeover provisions in our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our Class A common stock. Our third amended and restated certificate of incorporation **, as amended,** and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things, include: • a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; • a prohibition on stockholder actions through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; • a requirement that special meetings of stockholders be called only by our board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office; • advance notice requirements for stockholder proposals and nominations for election to our board of directors; • a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; • a requirement of approval of not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and • the authority of our board of directors to issue preferred stock on terms determined by our board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock. In addition, Section 203 of the General Corporation Law of the State of Delaware (the DGCL) ~~,~~ prohibits a publicly- held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15 % of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Any provision of our third amended and restated certificate of incorporation, **as amended, our** amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock. Our bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our third amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (the Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U. S. shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (the Federal Forum Provision). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit

our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were " facially valid " under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the U. S. may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.